Protocol: DUAG-7001

WebEZ System User Guide

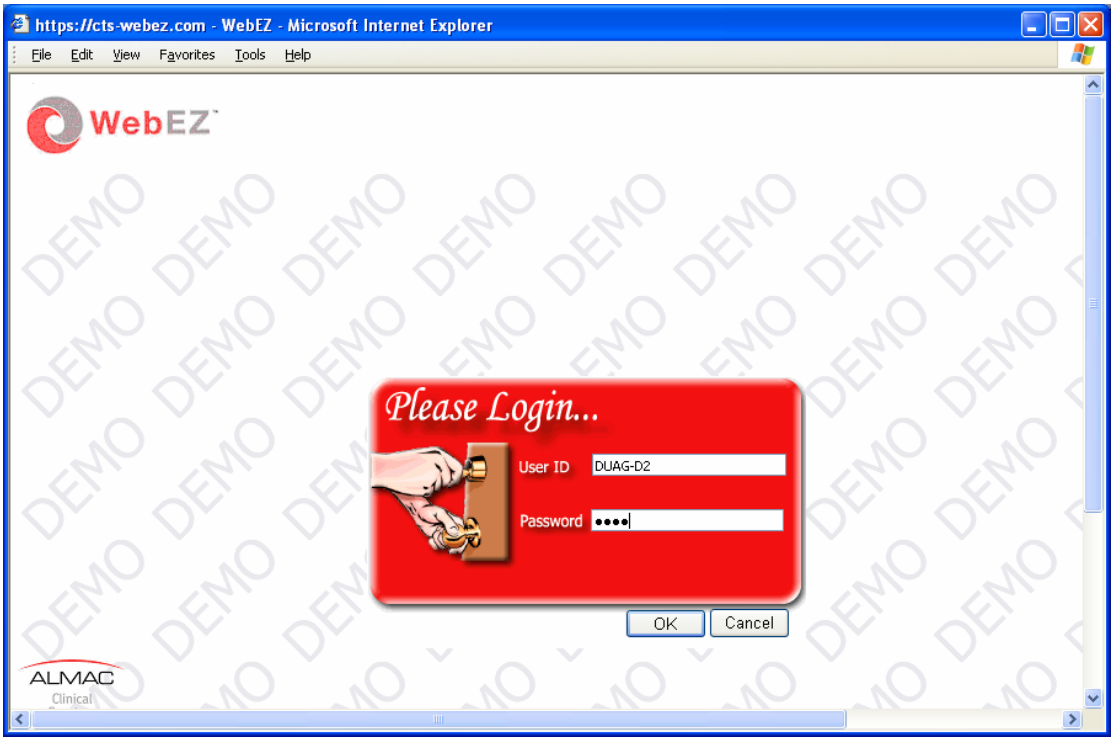
The **live website** for viewing patient and site data for the study is:
https://webez.almacgroup.com/webez/pages/webez.aspx

To use the **Demo system** for practice and training, connect to the following website:
https://webez.almacgroup.com/webeztest/pages/webez.aspx

(**Note**: the Demo system is a replica of the live system. The process is the same.)

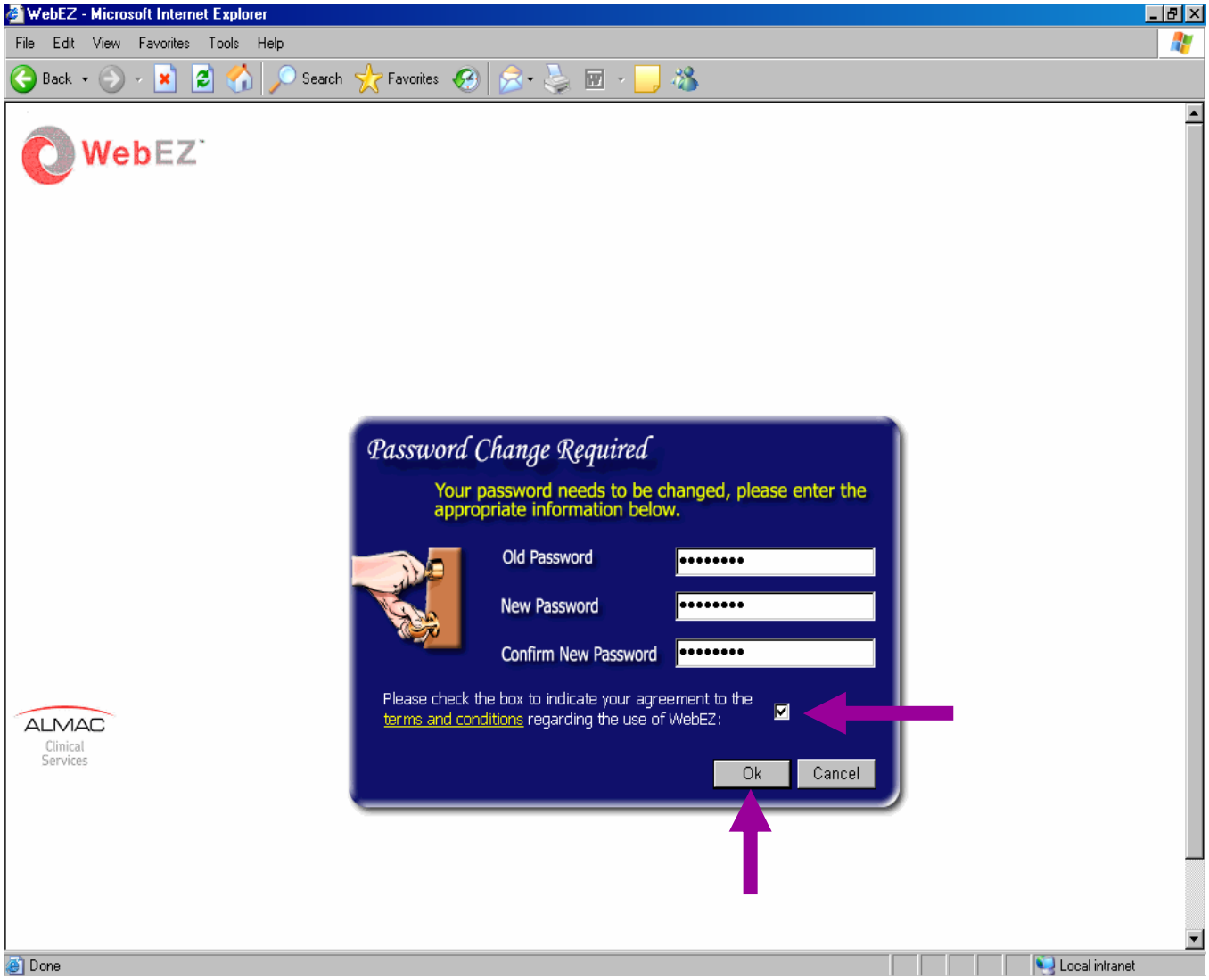
All pop-up blockers must be disabled for the WebEZ and WebEZ Demo sites.

You will see the following screen:



Enter the User ID: DUAG-7001
and Password: demo
Click on OK to log in.
Note that both the User ID and password are case sensitive.

After your first login to the live system, you will be prompted to change your password.

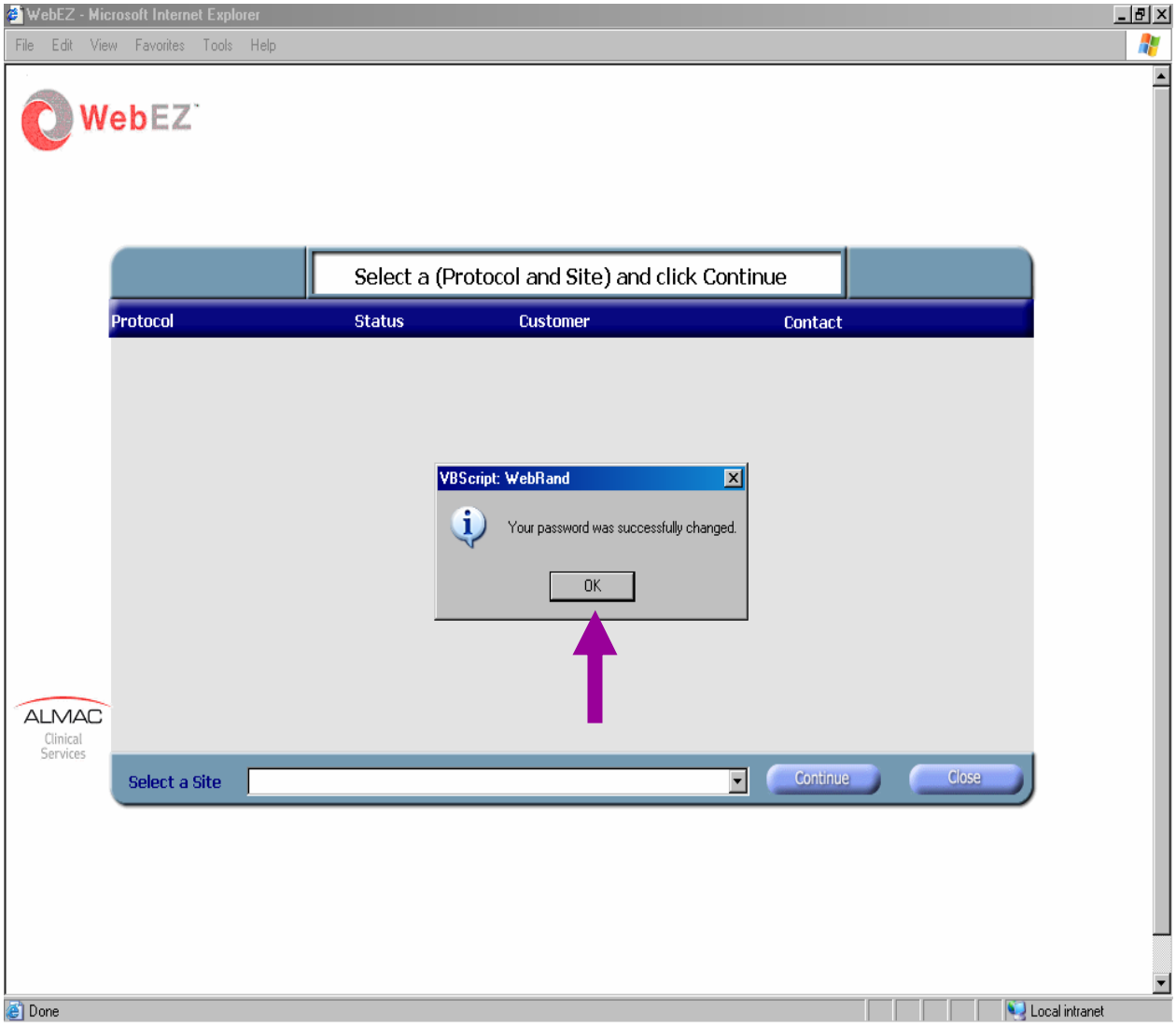


Your user ID and password for the live system will be sent via e-mail. An example of this email will look like:

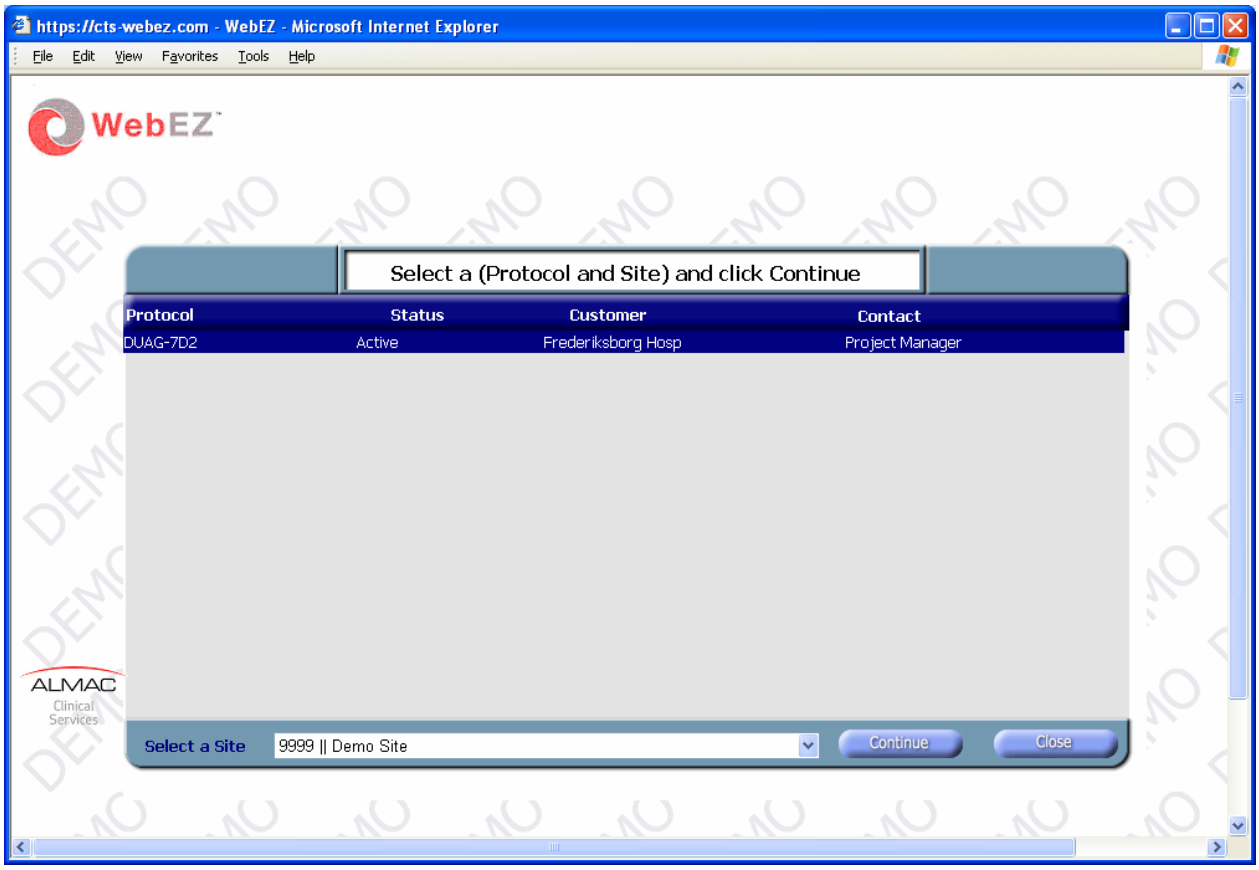
Welcome to the Almac Clinical Services - WebEZ system! To access WebEZ, please use the following Userid and Password. If you have any questions, please contact your Almac Clinical Services Project Manager.
Userid: SampleClient
Password: oW8p3Nf3

Your user ID will consist of lower case letters from your first and last name, followed by numbers, typically 001 or 002. Your initial password will be a temporary one that you will be prompted to change the first time you log in, Passwords must be at least 8 characters long. Click on ñOKò after entering your new password information, and indicating your agreement to the ñTerms and Conditionsò of WebEZ use.

A message will appear to confirm that your password was changed. Click ñOKò on the message.

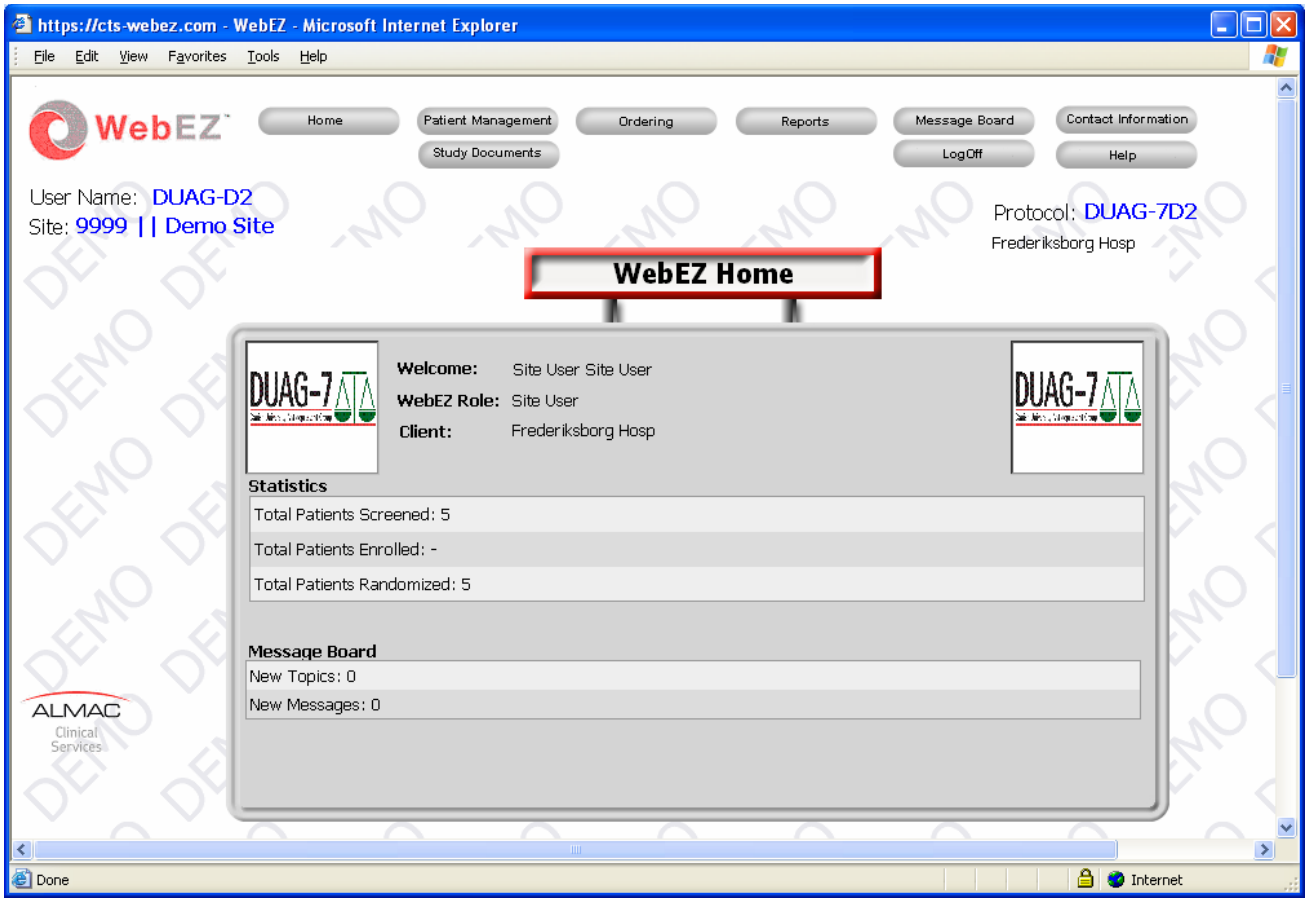


Select the site number from the drop down list at the bottom of the screen and click ñContinueò. In the Demo system the site number is always 9999.

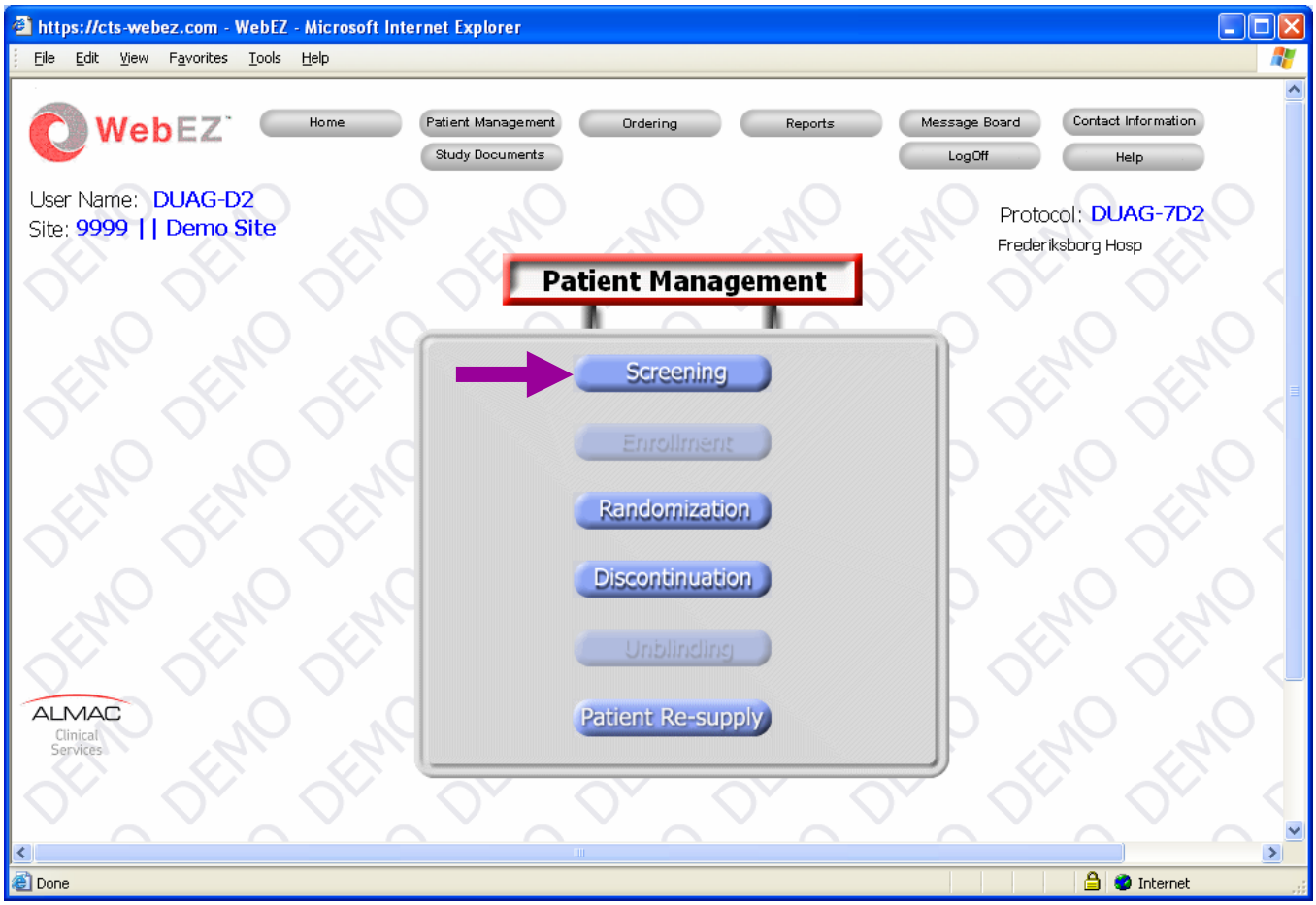


Everyone uses the same Demo system. In the live system, sites will only have access to the data for their site. Client users will have access to data for all sites.

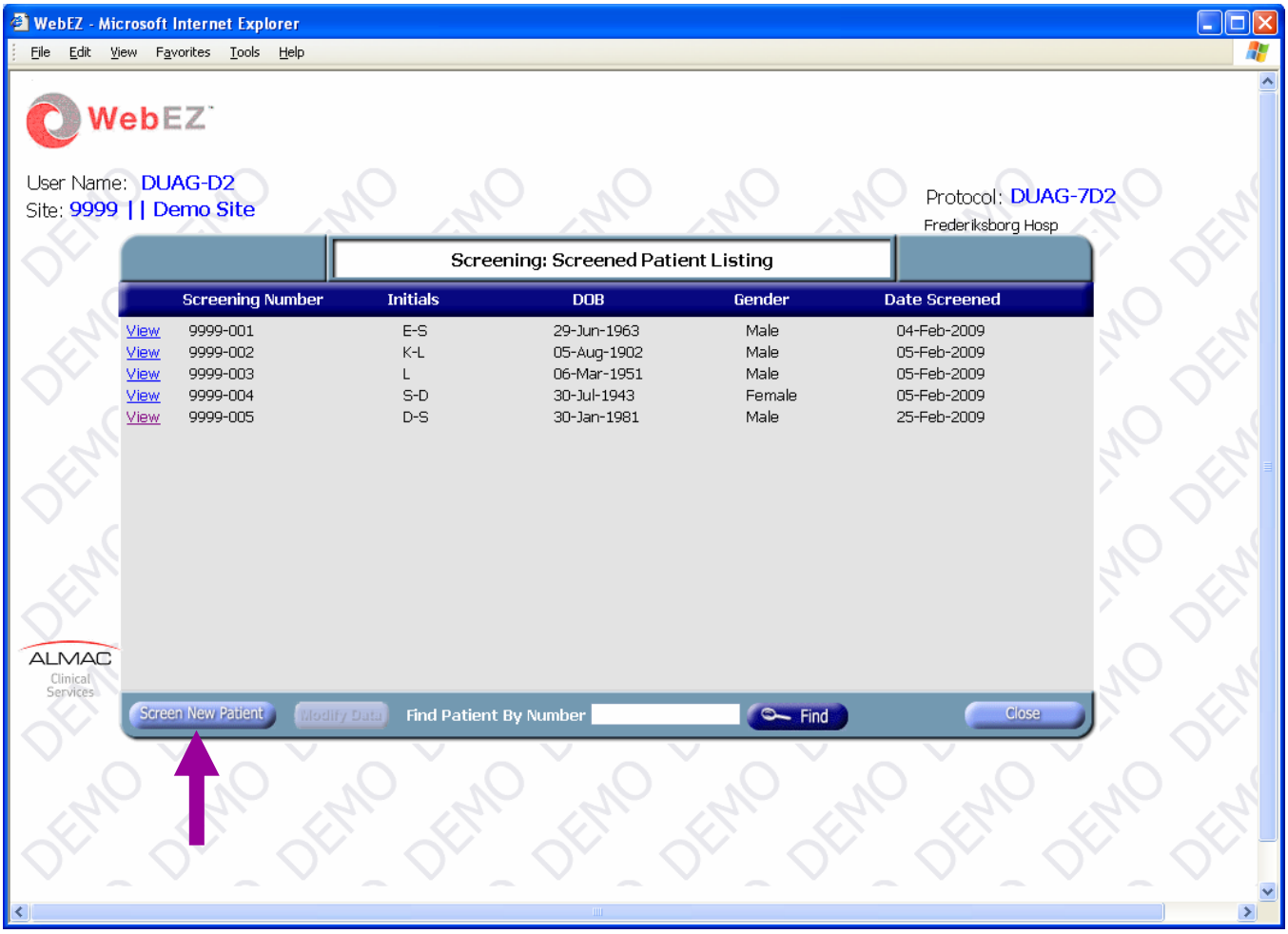
This will take you to the home page for the study. At the top of the home page you will see various action buttons. Click on the ñPatient Managementò button.



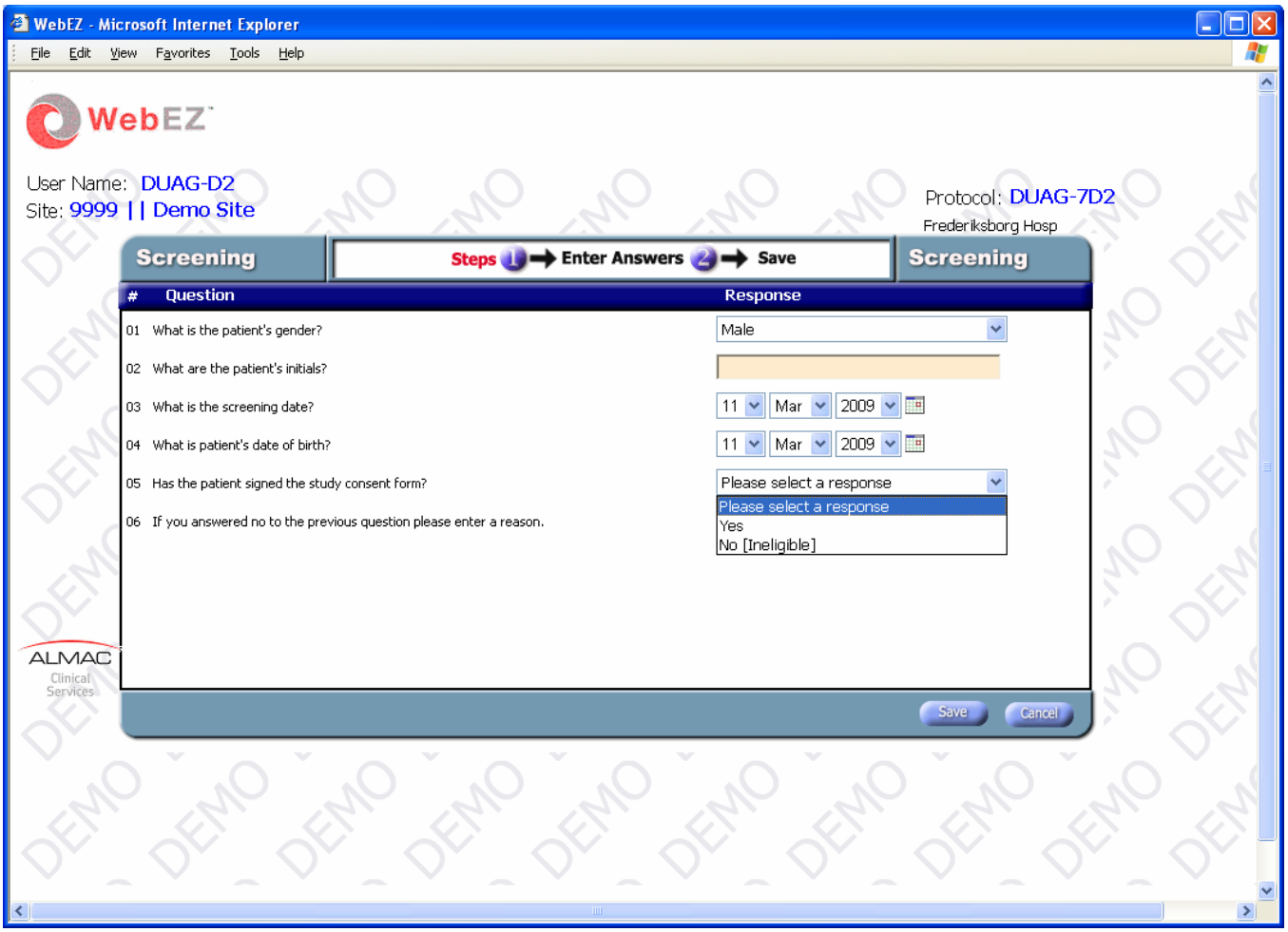
Click on ñScreeningò to enter or view screening data for your patient.



To enter a new patient, click on ñScreen New Patientò.

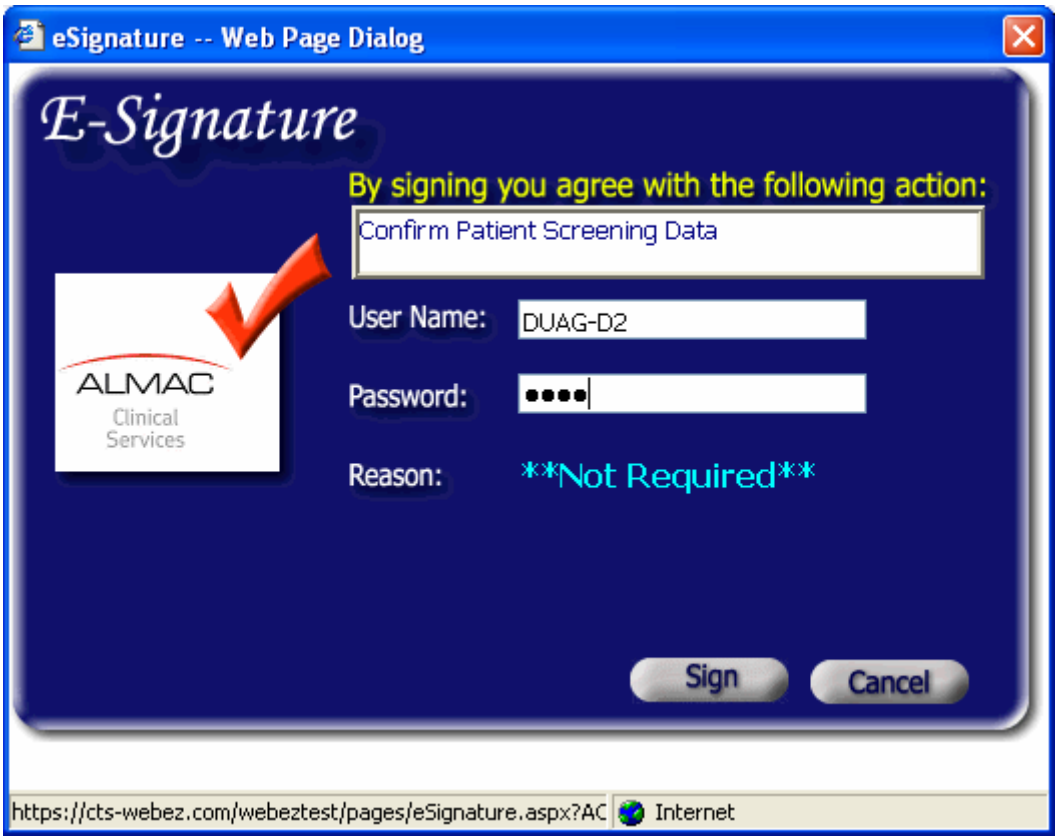


Answer the questions about your patient.



All the drop down questions will be pre-populated with default responses. These default responses must be reviewed and corrected before the patient data is saved. Use the drop down arrows to change the responses for the patientôs gender, screening date and eligibility status.

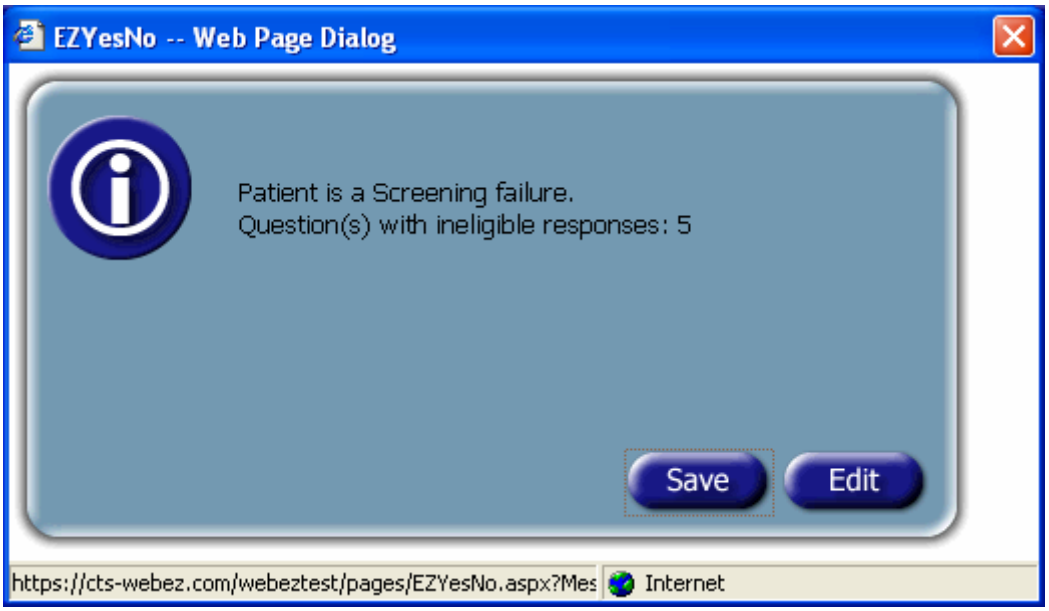
You will be asked to e-sign for the patient data. Your e-signature is your User ID and password. Click on ñSignò.



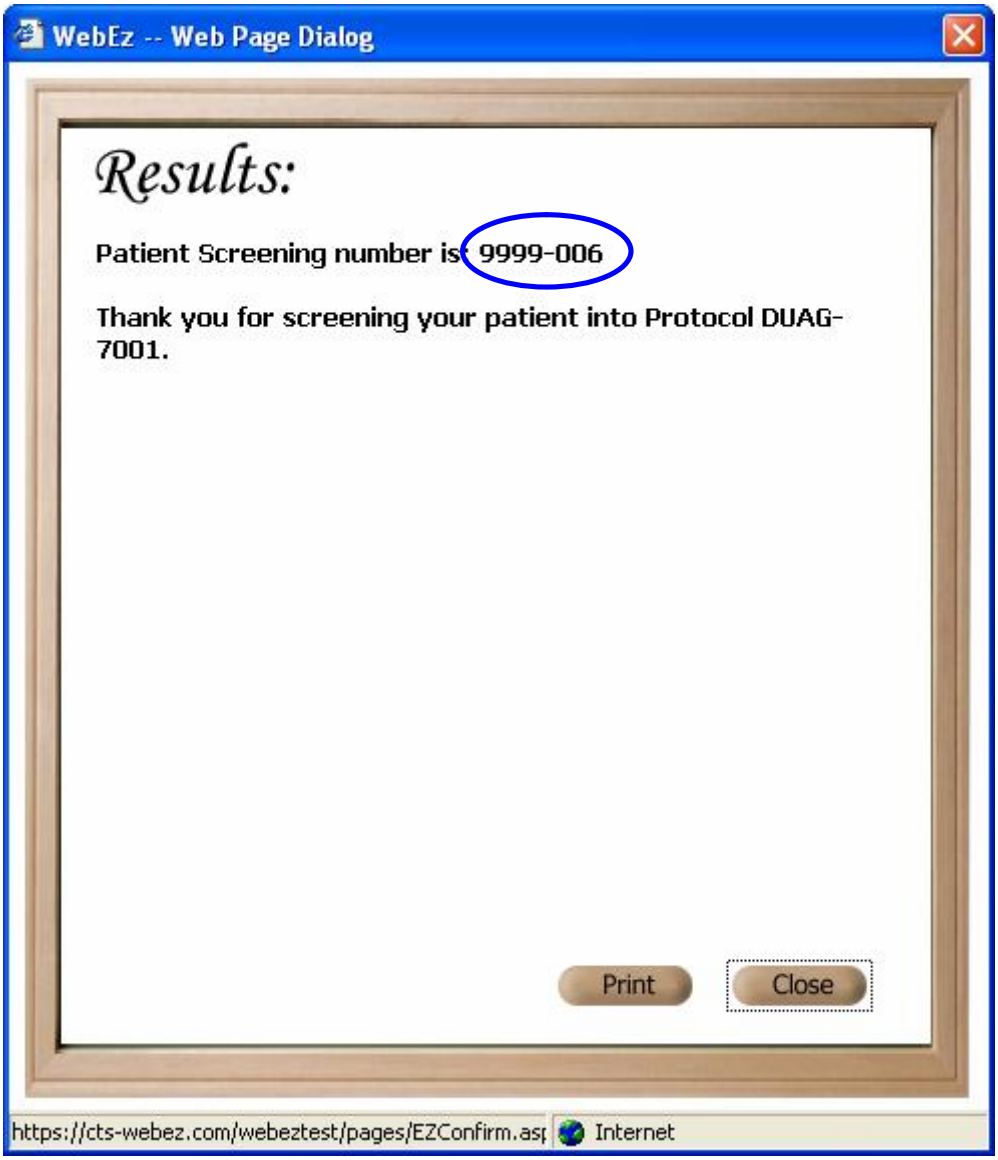
Electronic signatures are considered the same as a hard copy signature, and should be regarded as such. Do not share your e-signature (User ID and password). Each person at your site who needs to use the WebEZ system must do so using his/her own WebEZ account.

By answering No to Question 5 the below pop up window will appear.

Click Save to continue saving the data.



Once the data is saved the Results screen will appear with the patient screening number.

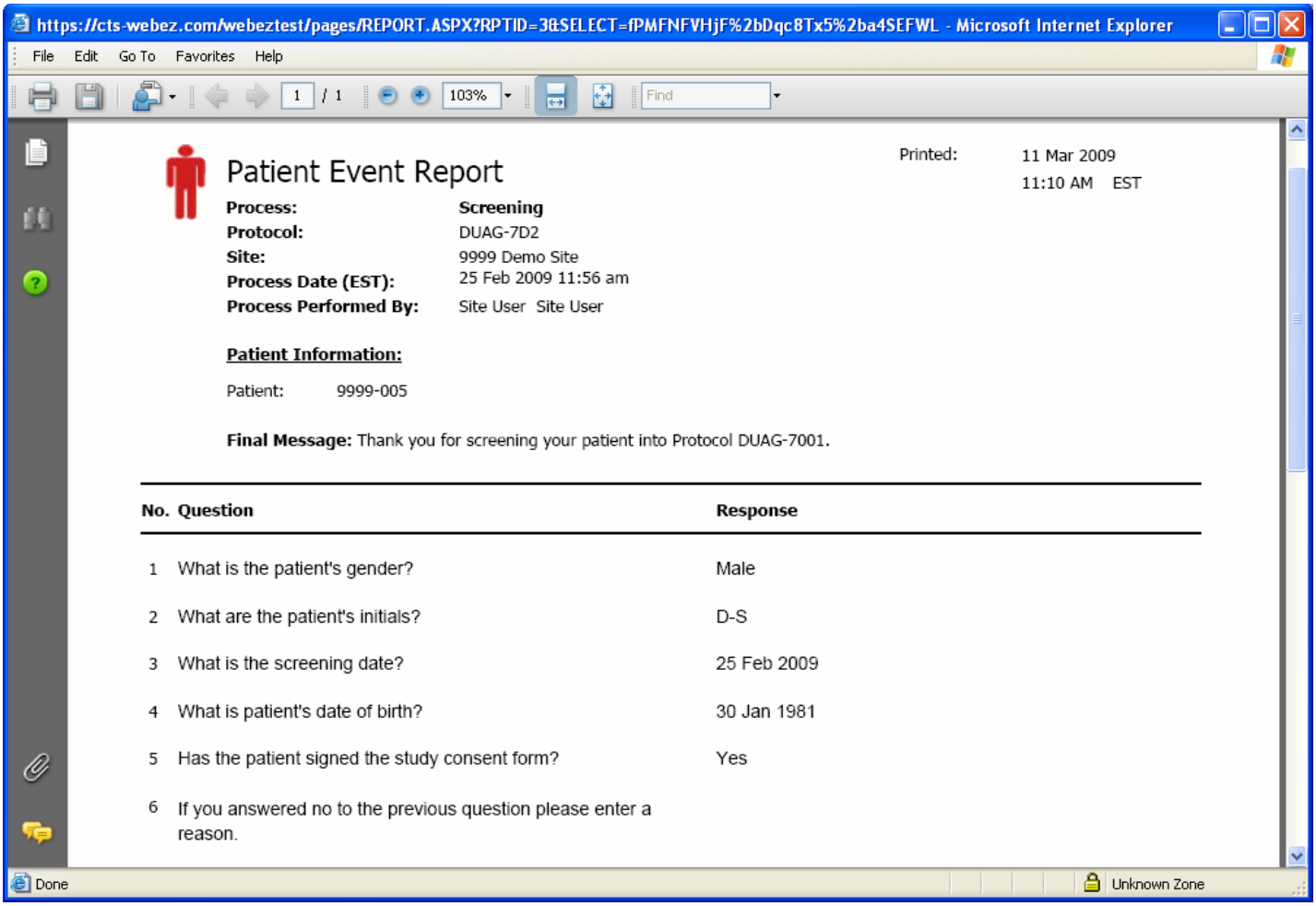


Close the Results window to return to the Screened Patient Listing.

To view the data for an existing patient click on the word ñViewò next to the patient details.

https://cts-webez.com - WebEZ - Microsoft Internet Explorer
File Edit View Favorites Tools Help
WebEZ
User Name: DUAG-D2
Site: 9999 | | Demo Site
Protocol: DUAG-7D2
Frederiksborg Hosp
Screening: Screened Patient Listing
Screening Number Initials DOB Gender Date Screened
View 9999-001 E-S 29-Jun-1963 Male 04-Feb-2009
View 9999-002 K-L 05-Aug-1902 Male 05-Feb-2009
View 9999-003 L 06-Mar-1951 Male 05-Feb-2009
View 9999-004 S-D 30-Jul-1943 Female 05-Feb-2009
View 9999-005 D-S 30-Jan-1981 Male 25-Feb-2009
View 9999-006 D-F 28-Nov-1959 Male 11-Mar-2009
ALMAC Clinical Services
Screen New Patient
Modify Data
Find Patient By Number
Find
Close

A new window will open with the Patient Event Report.


https://cts-webez.com/webeztest/pages/REPORT.ASPX?RPTID=3&SELECT=fPMFNFVHjF%2bDqc8Tx5%2ba4SEFWL - Microsoft Internet Explorer
File Edit Go To Favorites Help
Patient Event Report
Printed: 11 Mar 2009 11:10 AM EST
Process: Screening
Protocol: DUAG-7D2
Site: 9999 Demo Site
Process Date (EST): 25 Feb 2009 11:56 am
Process Performed By: Site User Site User
Patient Information:
Patient: 9999-005
Final Message: Thank you for screening your patient into Protocol DUAG-7001.
No. Question Response
1 What is the patient's gender? Male
2 What are the patient's initials? D-S
3 What is the screening date? 25 Feb 2009
4 What is patient's date of birth? 30 Jan 1981
5 Has the patient signed the study consent form? Yes
6 If you answered no to the previous question please enter a reason.
Done
Unknown Zone

Please print this report and save with your source study documents.

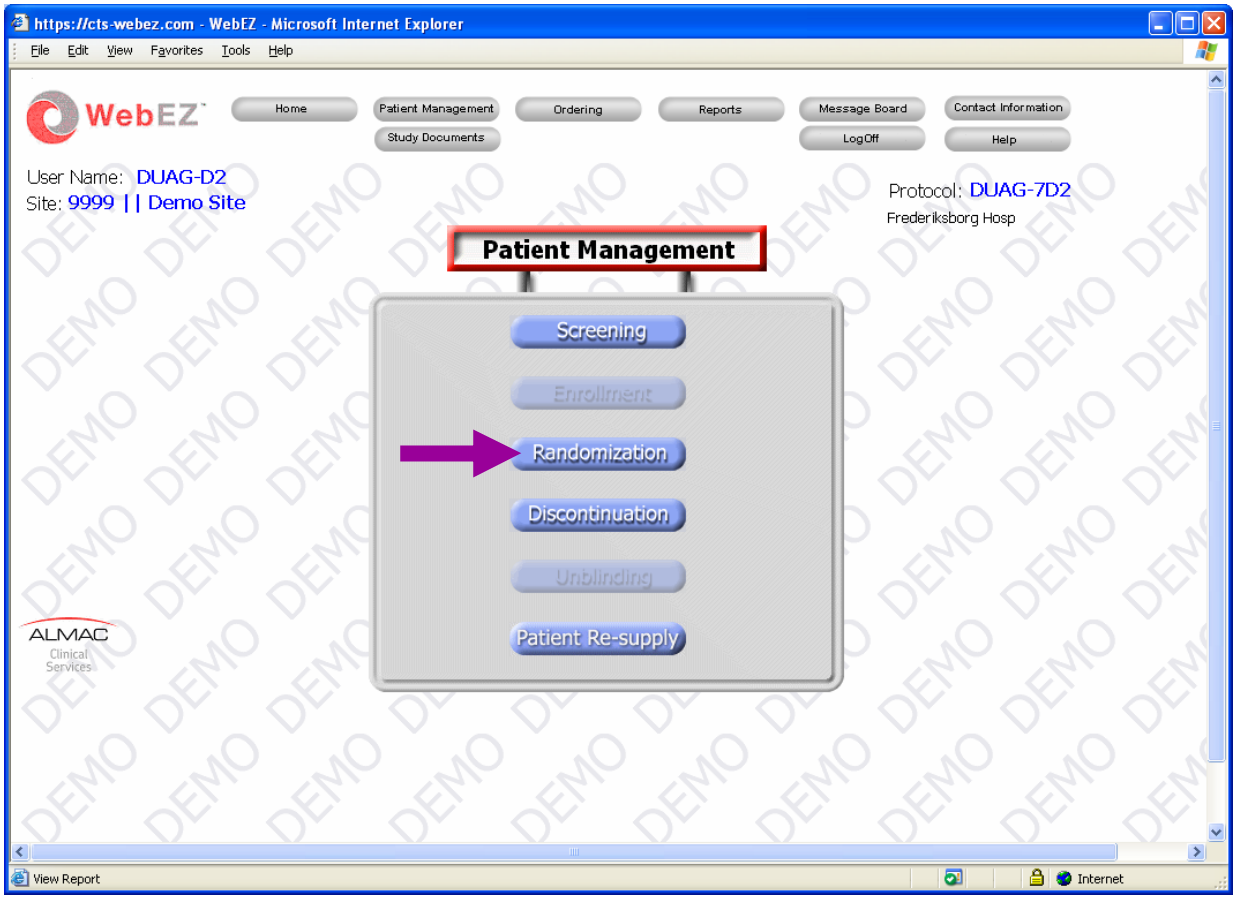
Once the patient has completed the screening process if you need to modify the demographic information e.g. Date of birth was entered incorrectly, select the patient and click on the ñModify Dataò button. Make the changes to the answer and click save. Enter your e-signature to save the data.

https://cts-webez.com - WebEZ - Microsoft Internet Explorer
File Edit View Favorites Tools Help
WebEZ
User Name: DUAG-D2
Site: 9999 | | Demo Site
Protocol: DUAG-7D2
Frederiksborg Hosp
Screening: Screened Patient Listing
Screening Number Initials DOB Gender Date Screened
View 9999-001 E-S 29-Jun-1963 Male 04-Feb-2009
View 9999-002 K-L 05-Aug-1902 Male 05-Feb-2009
View 9999-003 L 06-Mar-1951 Male 05-Feb-2009
View 9999-004 S-D 30-Jul-1943 Female 05-Feb-2009
View 9999-005 D-S 30-Jan-1981 Male 25-Feb-2009
View 9999-006 D-F 28-Nov-1959 Male 11-Mar-2009
ALMAC Clinical Services
Screen New Patient
Modify Data
Find Patient By Number
Find
Close
View Report
Internet

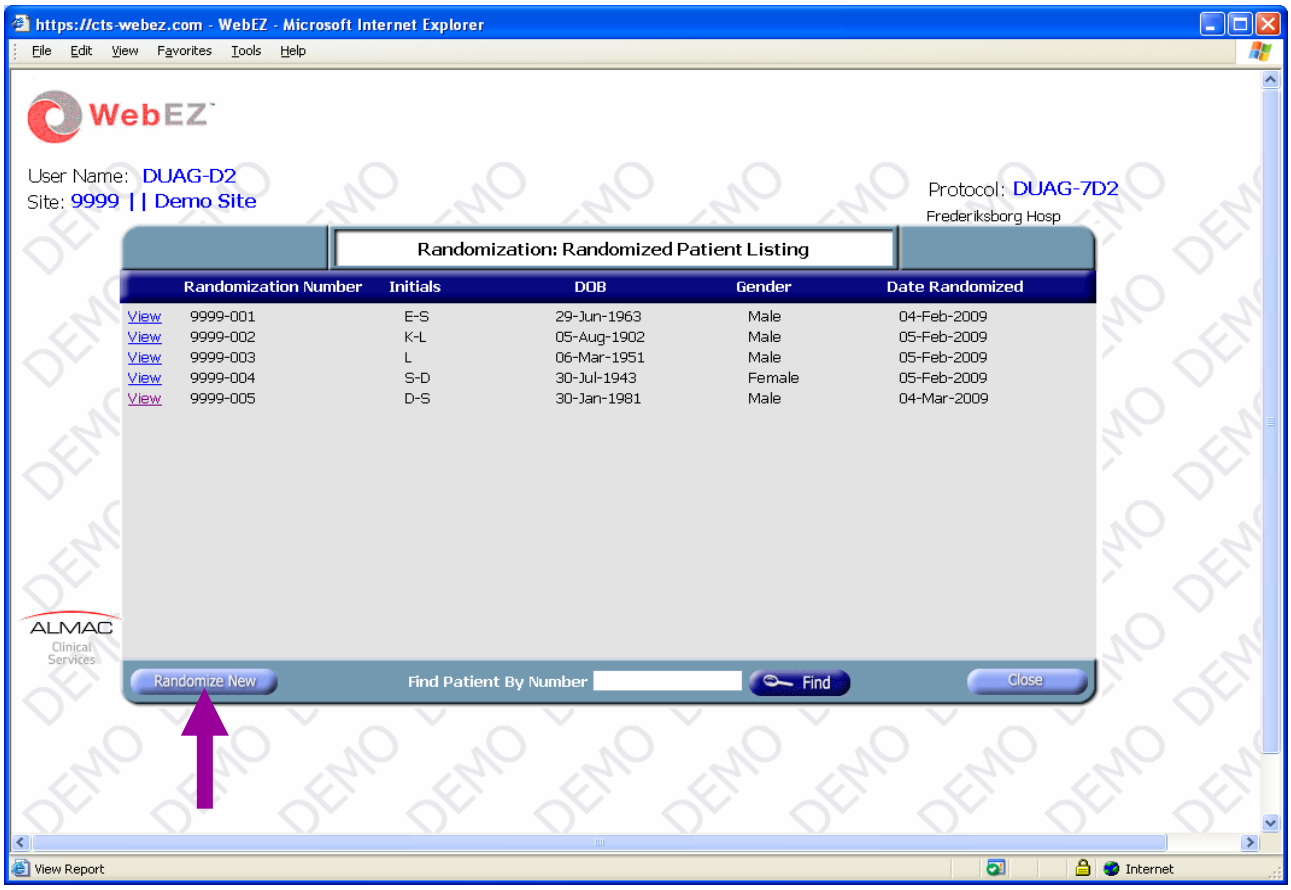
Please note the response to Question 3 ñWhat is the screening date?ò should not be modified. This date should always be the date that consent was obtained.

Click on the close button to exit screening.

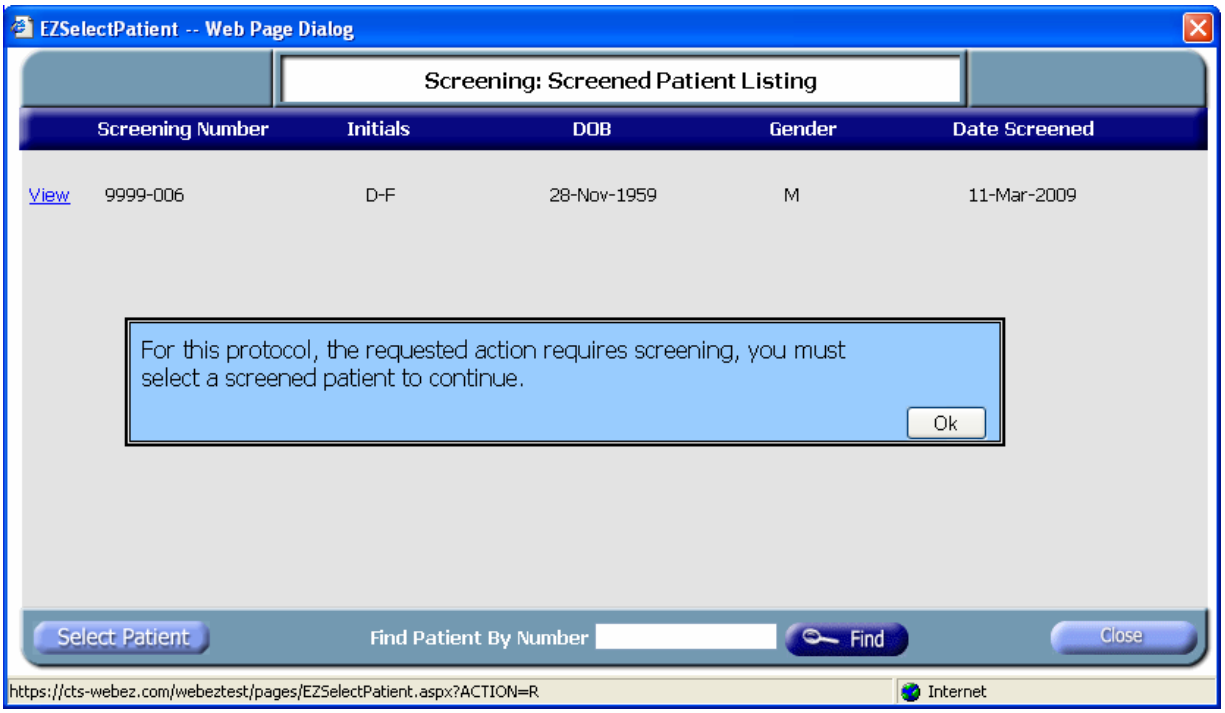
Click on Randomization to obtain the treatment assignment for eligible patients.



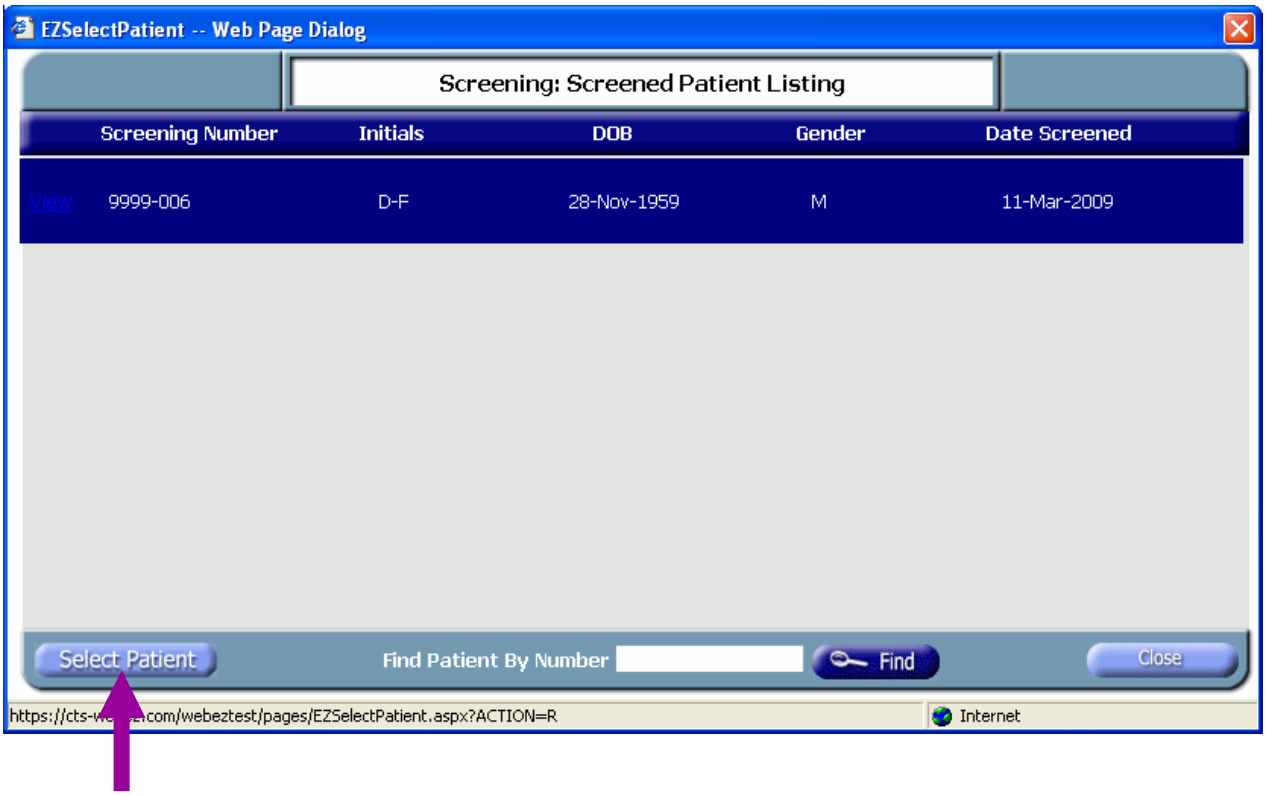
To randomize a new patient click on ñRandomize Newò.



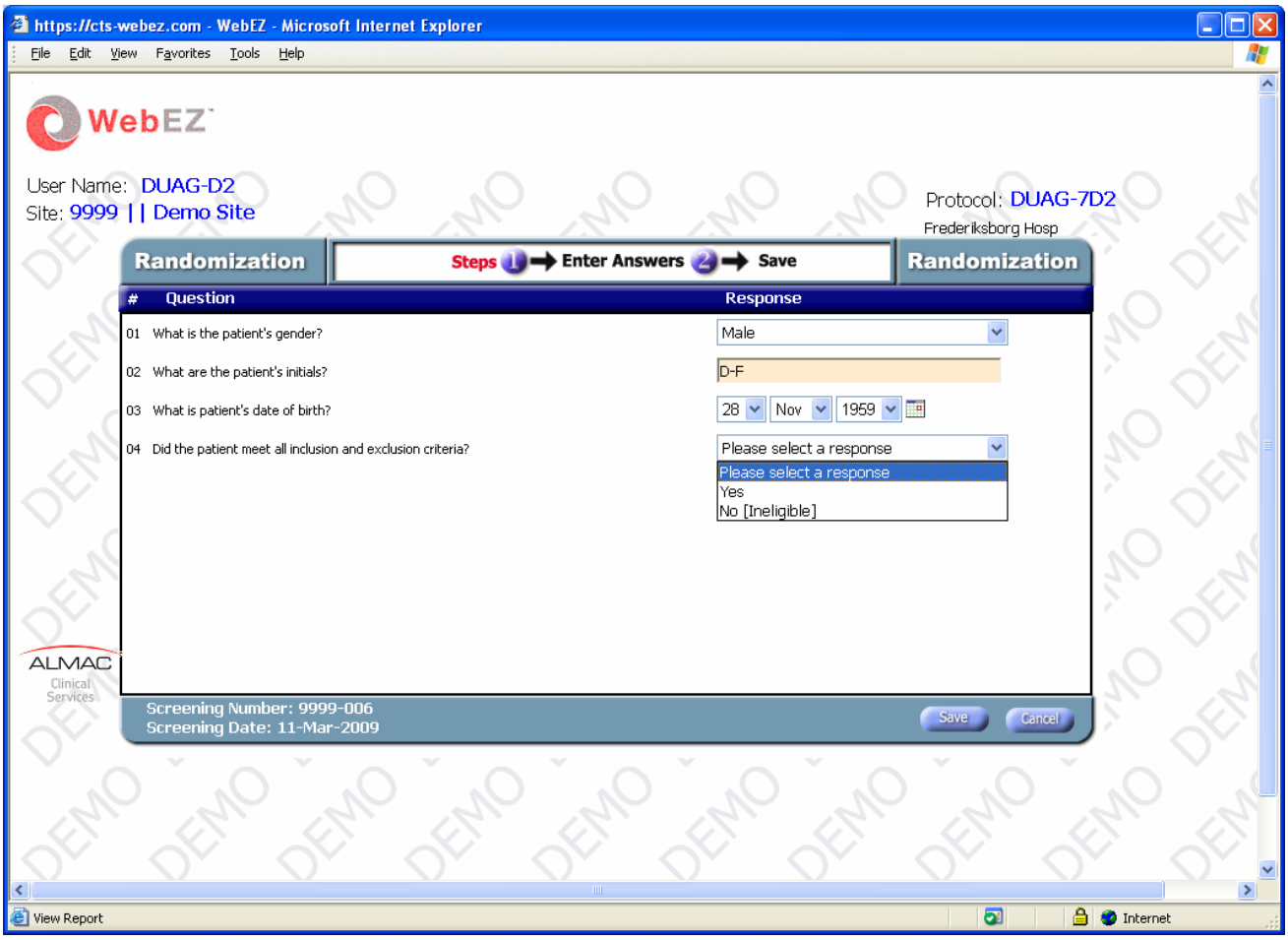
You must select a screened patient to Randomize. Click ñOKò on the reminder message.



Select a patient by clicking on the initials and highlighting the record. Then click on ñSelect Patientò.



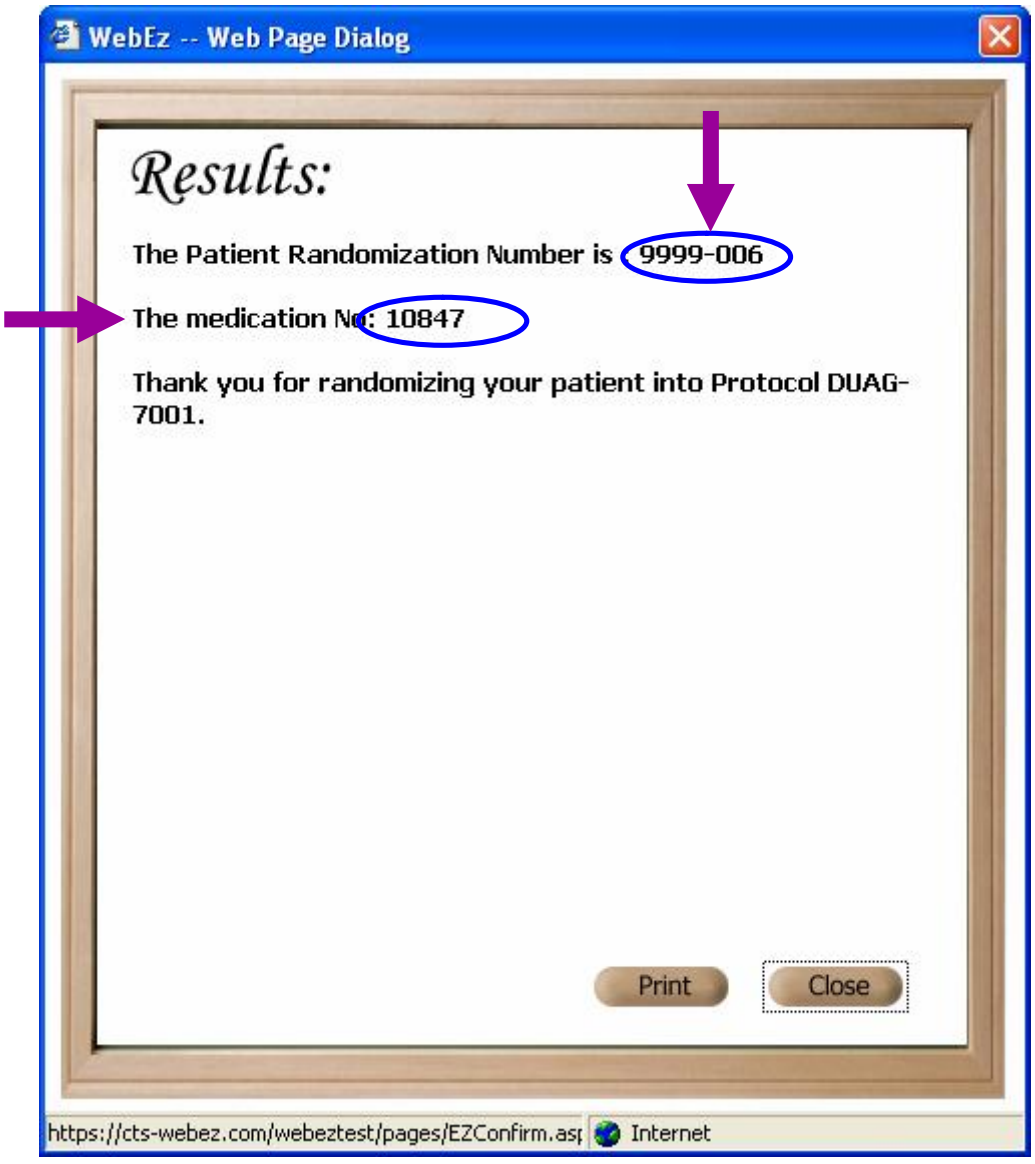
Verify the patientôs initials, date of birth and gender from screening.



Once you have answered all questions for your patient click on ñSaveò.

You will be asked to e-sign for the patient data.

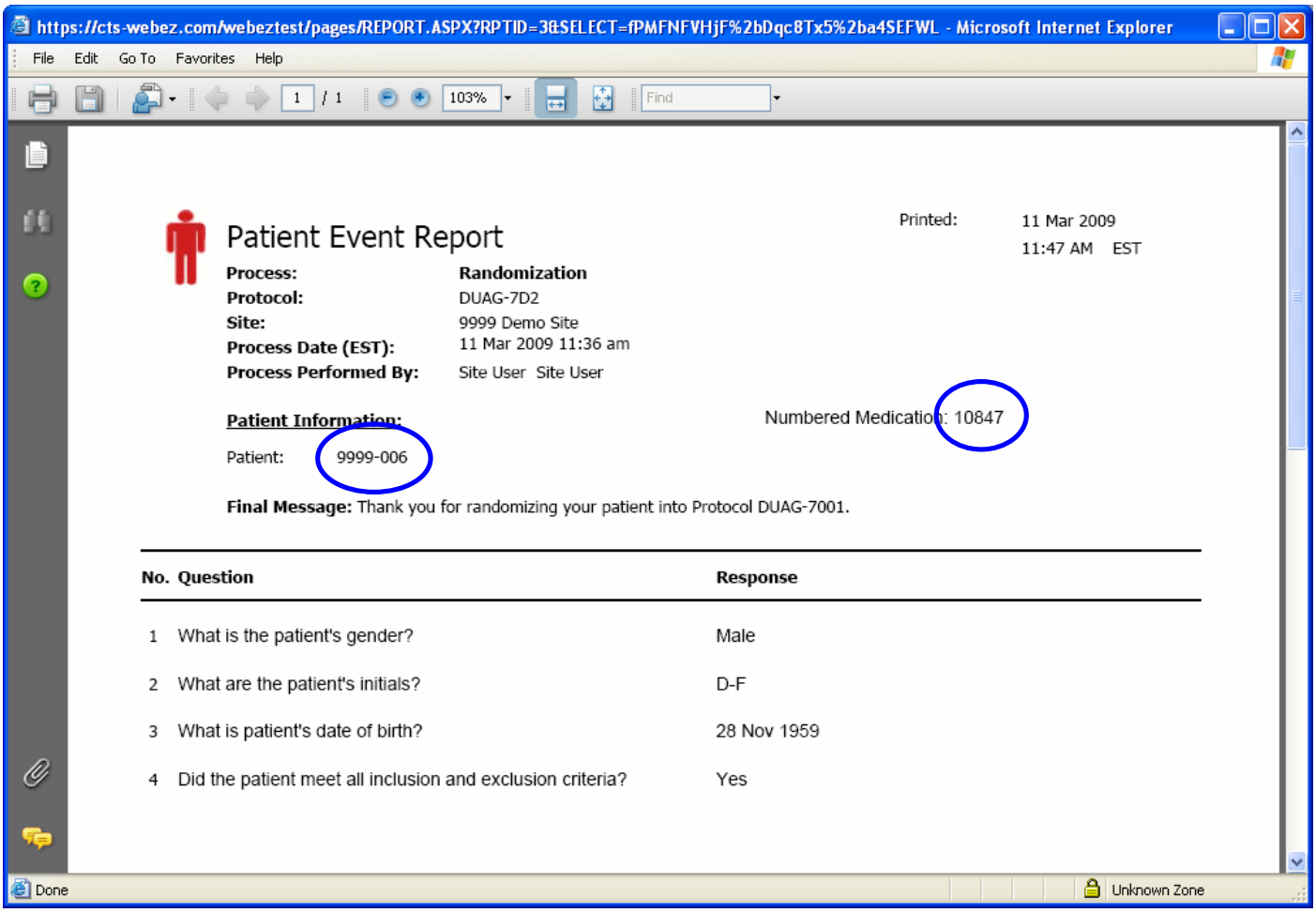
Once the patient data is saved, the Results screen will appear with the patientôs randomization number and medication number. The patient is assigned one kit at Randomization which contains 1 up titration wallet card to cover week 1 and 12 fixed wallet cards for weeks 2-25.



To view the data for an existing patient click on the word ñViewò next to the patient number.

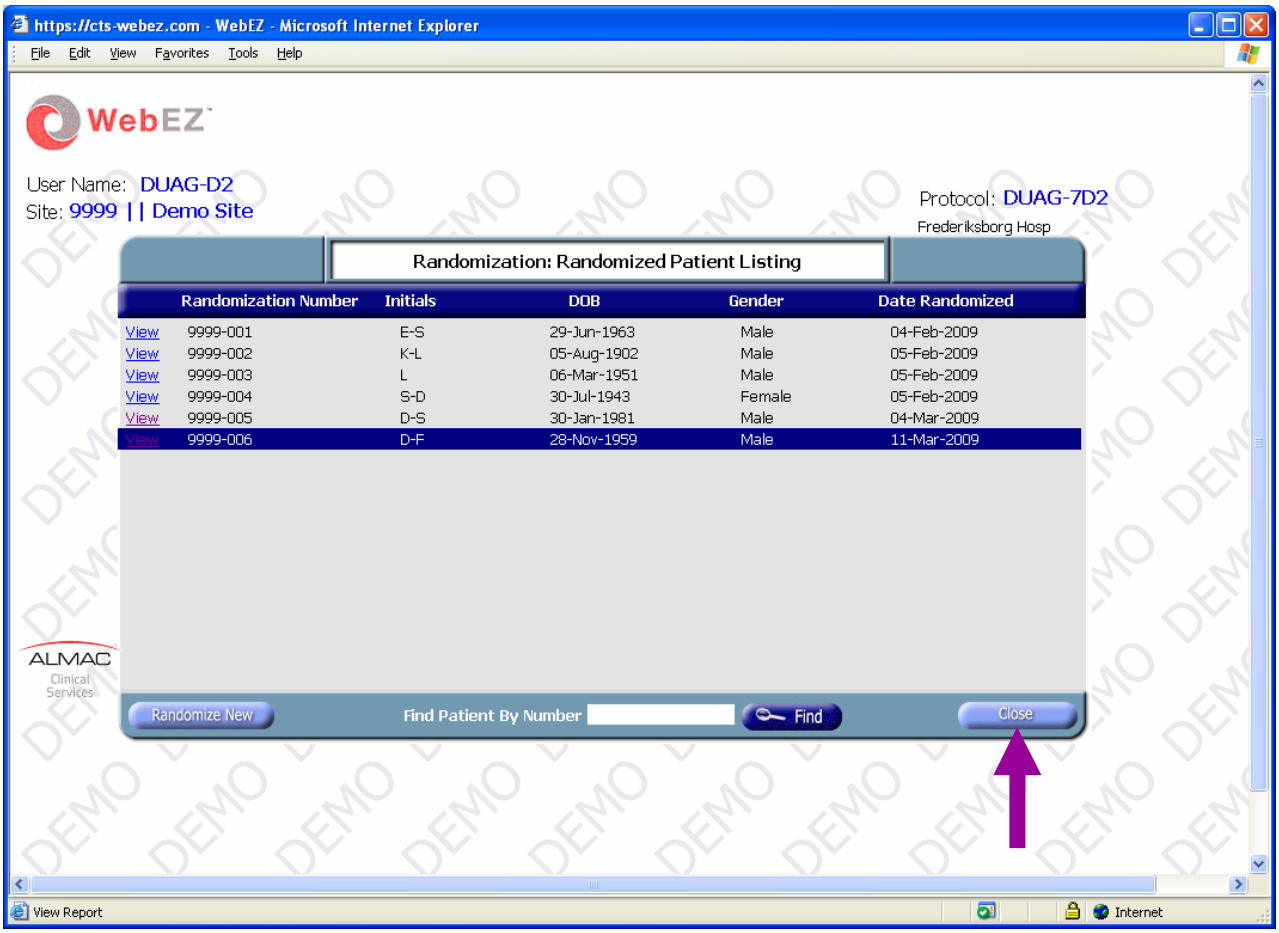
https://cts-webez.com - WebEZ - Microsoft Internet Explorer
File Edit View Favorites Tools Help
WebEZ
User Name: DUAG-D2
Site: 9999 || Demo Site
Protocol: DUAG-7D2
Frederiksborg Hosp
Randomization: Randomized Patient Listing
Randomization Number Initials DOB Gender Date Randomized
View 9999-001 E-S 29-Jun-1963 Male 04-Feb-2009
View 9999-002 K-L 05-Aug-1902 Male 05-Feb-2009
View 9999-003 L 06-Mar-1951 Male 05-Feb-2009
View 9999-004 S-D 30-Jul-1943 Female 05-Feb-2009
View 9999-005 D-S 30-Jan-1981 Male 04-Mar-2009
View 9999-006 D-F 28-Nov-1959 Male 11-Mar-2009
ALMAC Clinical Services
Randomize New
Find Patient By Number
Find
Close
View Report
Internet

A new window will open with the Patient Event Report.

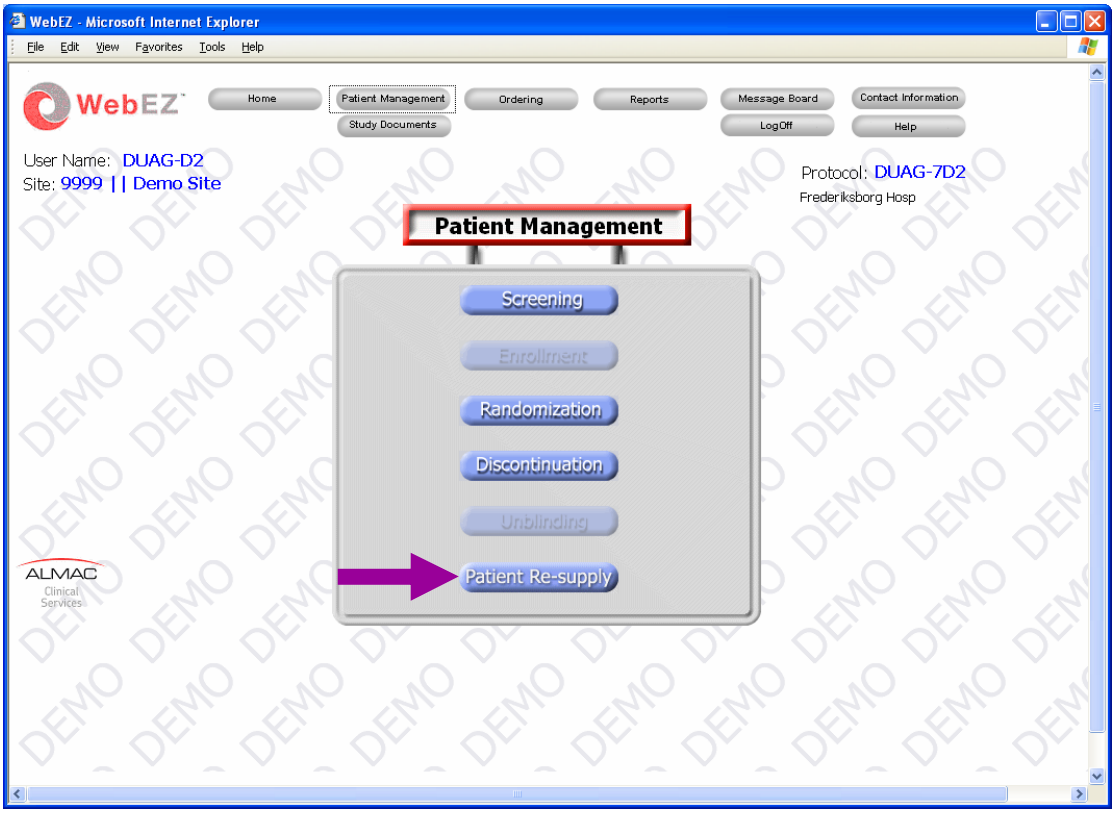

https://cts-webez.com/webeztest/pages/REPORT.ASPX?RPTID=3&SELECT=fPMFNFVHjF%2bDqc8Tx5%2ba4SEFWL - Microsoft Internet Explorer
File Edit Go To Favorites Help
Patient Event Report
Printed: 11 Mar 2009 11:47 AM EST
Process: Randomization
Protocol: DUAG-7D2
Site: 9999 Demo Site
Process Date (EST): 11 Mar 2009 11:36 am
Process Performed By: Site User Site User
Patient Information:
Numbered Medication: 10847
Patient: 9999-006
Final Message: Thank you for randomizing your patient into Protocol DUAG-7001.
No. Question Response
1 What is the patient's gender? Male
2 What are the patient's initials? D-F
3 What is patient's date of birth? 28 Nov 1959
4 Did the patient meet all inclusion and exclusion criteria? Yes
Done
Unknown Zone

Please print this report and save with your source study documents.

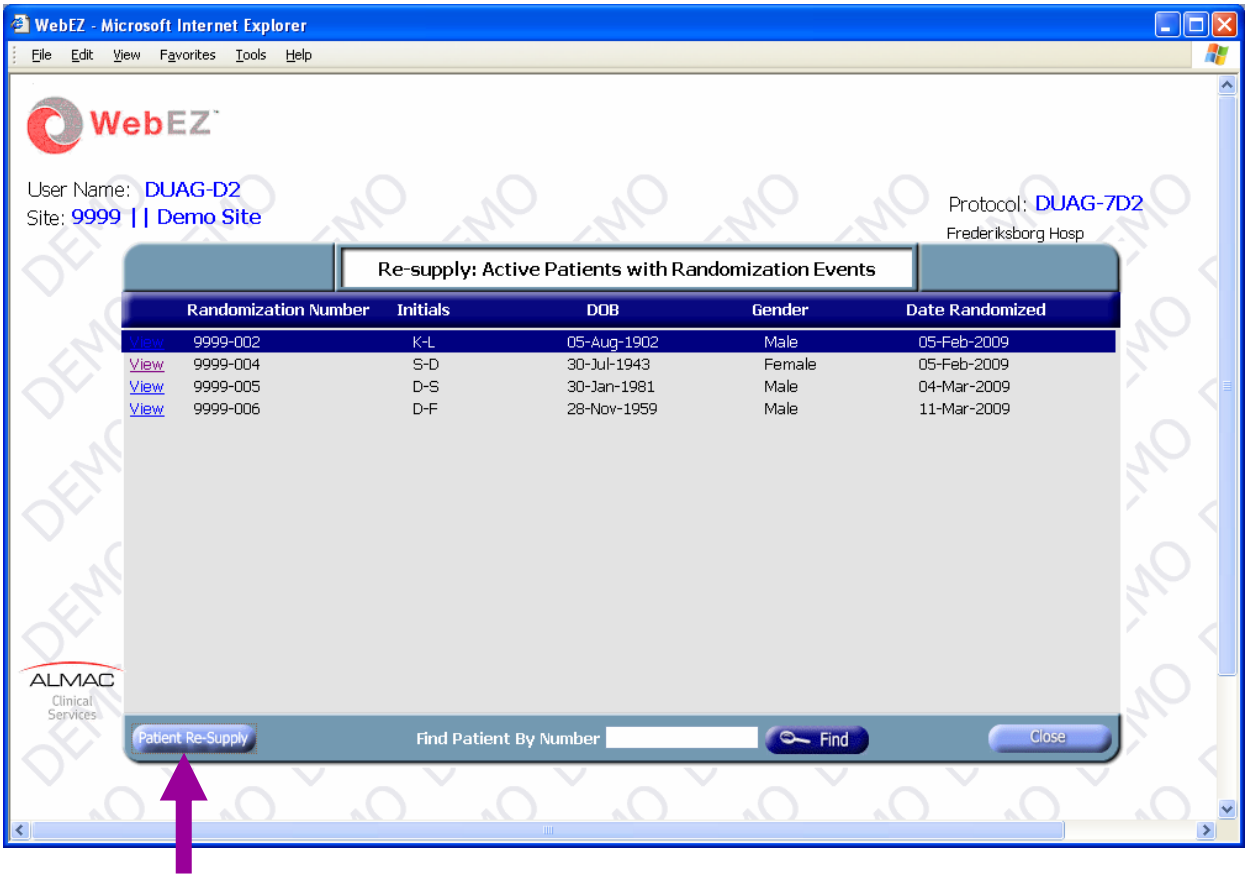
Click the ñCloseò button to exit Randomization.



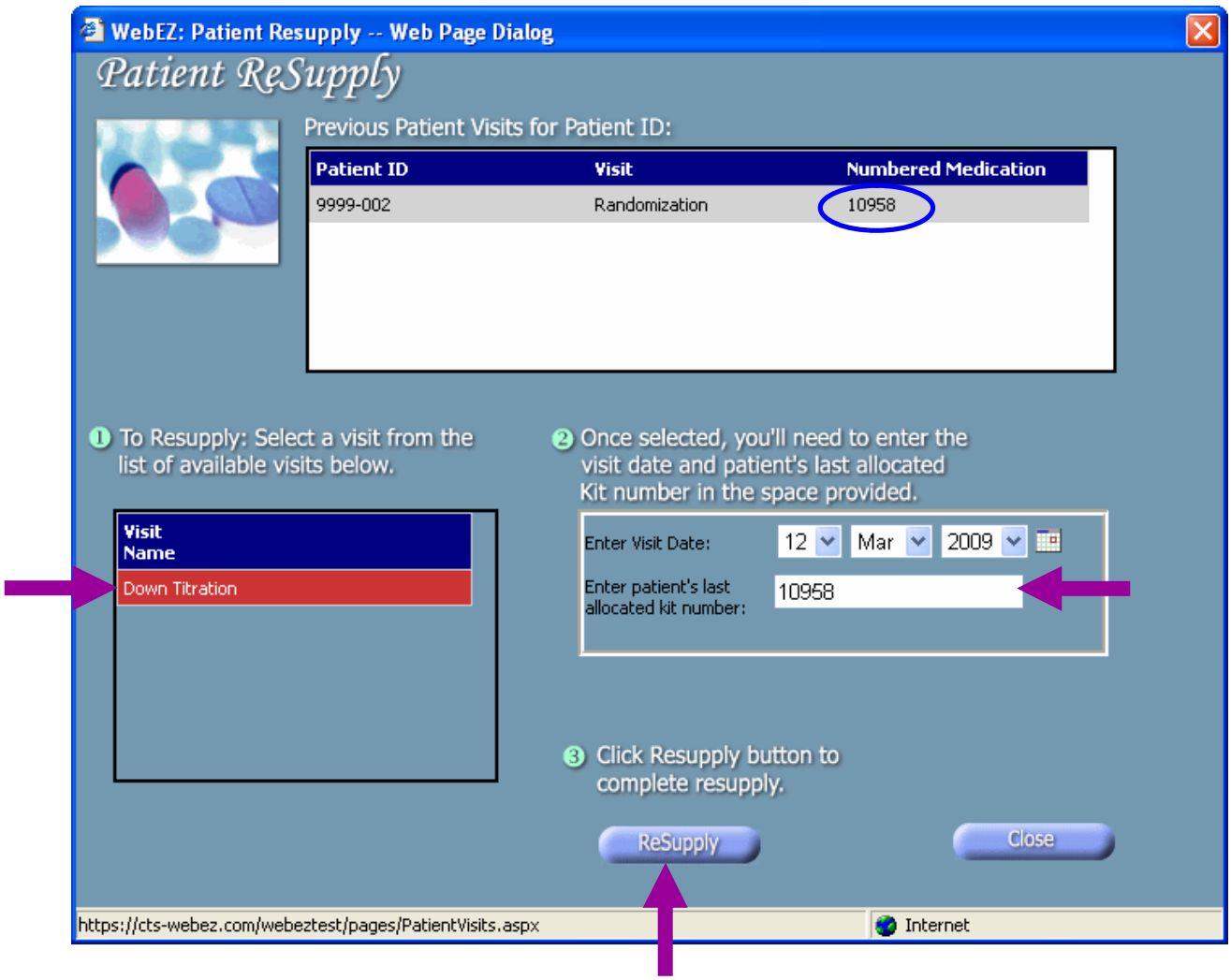
To obtain the down titration medication for patients, click on the ñPatient Re-Supplyò button.



Select the patient you want to re-supply by clicking on the patientôs initials. Click on ñPatient Re-Supplyò.


WebEZ - Microsoft Internet Explorer
File Edit View Favorites Tools Help
WebEZ
User Name: DUAG-D2
Site: 9999 | | Demo Site
Protocol: DUAG-7D2
Frederiksborg Hosp
Re-supply: Active Patients with Randomization Events
Randomization Number Initials DOB Gender Date Randomized
View 9999-002 K-L 05-Aug-1902 Male 05-Feb-2009
View 9999-004 S-D 30-Jul-1943 Female 05-Feb-2009
View 9999-005 D-S 30-Jan-1981 Male 04-Mar-2009
View 9999-006 D-F 28-Nov-1959 Male 11-Mar-2009
ALMAC Clinical Services
Patient Re-Supply
Find Patient By Number
Find
Close

Follow the 3 steps highlighted below to assign down titration medication (single wallet card) to your patient.
Verify that the Patient ID is correct and that the date of the patientôs visit is correct and enter the kit number dispensed to the patient at inclusion.

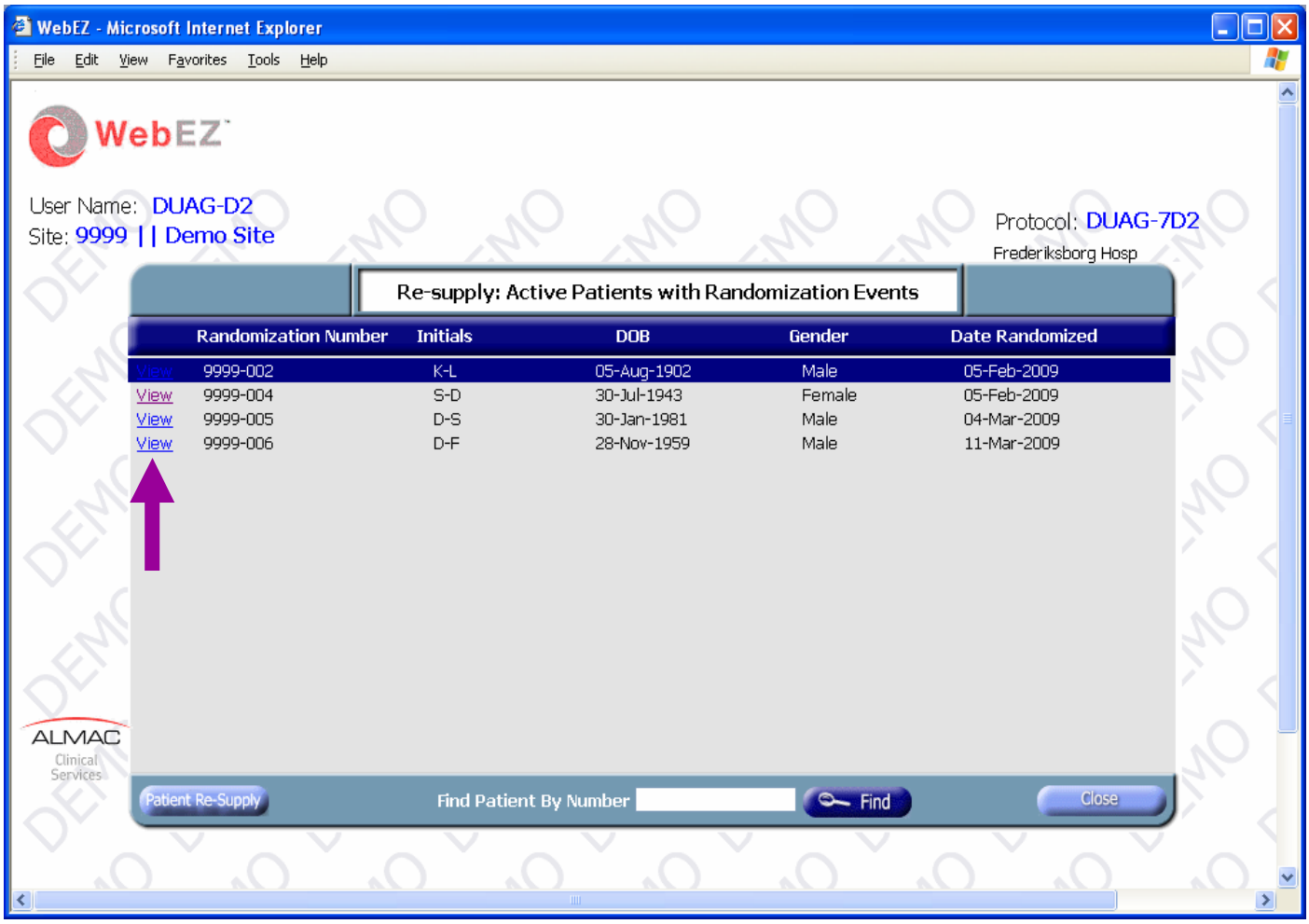


You will be asked for your e-signature and a reason. Click on ñSignò.

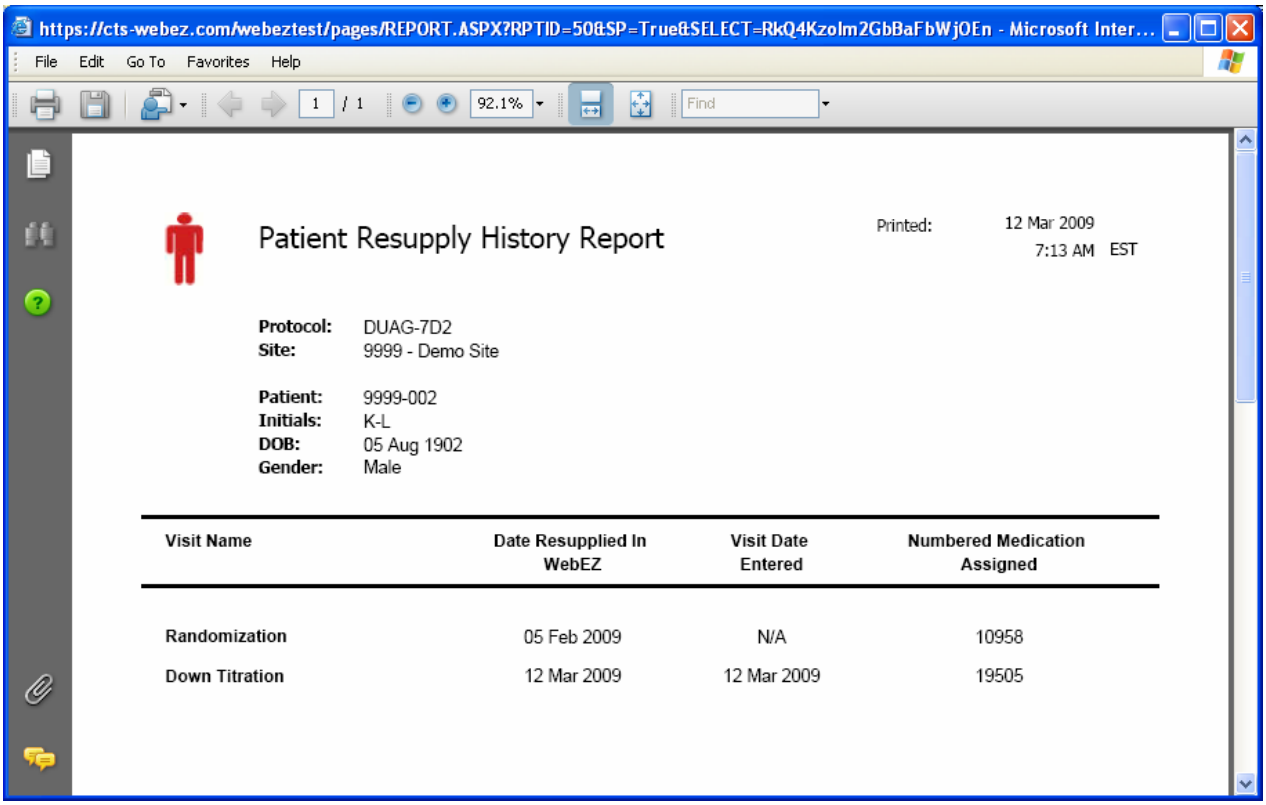
A Results window will pop up detailing the new Patient assignment.

Close the Results window to return to the Active Patient listing.

Click on ñViewò to the left of the patient number.

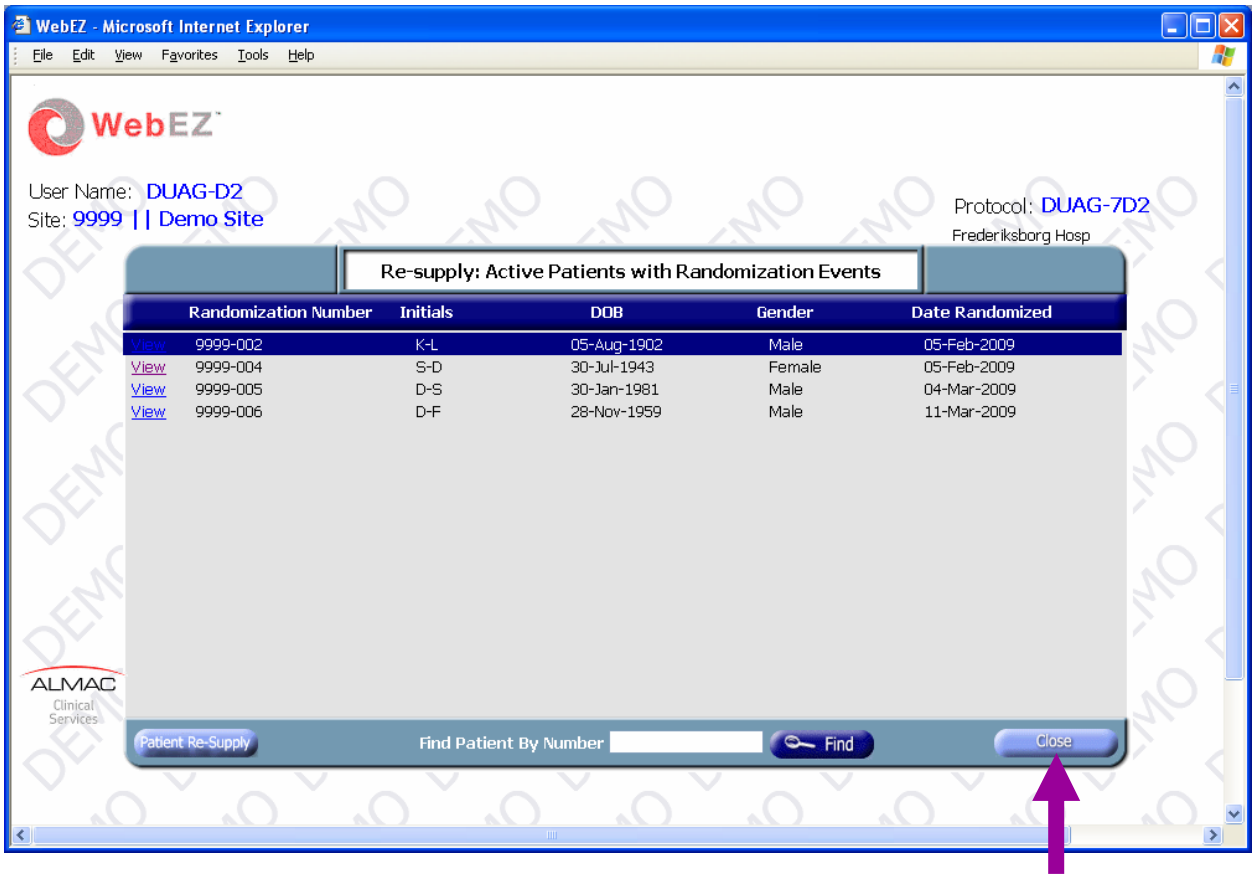

WebEZ - Microsoft Internet Explorer
File Edit View Favorites Tools Help
WebEZ
User Name: DUAG-D2
Site: 9999 || Demo Site
Protocol: DUAG-7D2
Frederiksborg Hosp
Re-supply: Active Patients with Randomization Events
Randomization Number Initials DOB Gender Date Randomized
View 9999-002 K-L 05-Aug-1902 Male 05-Feb-2009
View 9999-004 S-D 30-Jul-1943 Female 05-Feb-2009
View 9999-005 D-S 30-Jan-1981 Male 04-Mar-2009
View 9999-006 D-F 28-Nov-1959 Male 11-Mar-2009
ALMAC Clinical Services
Patient Re-Supply
Find Patient By Number
Find
Close

A new window will open with the ñPatient Resupply History Reportò.

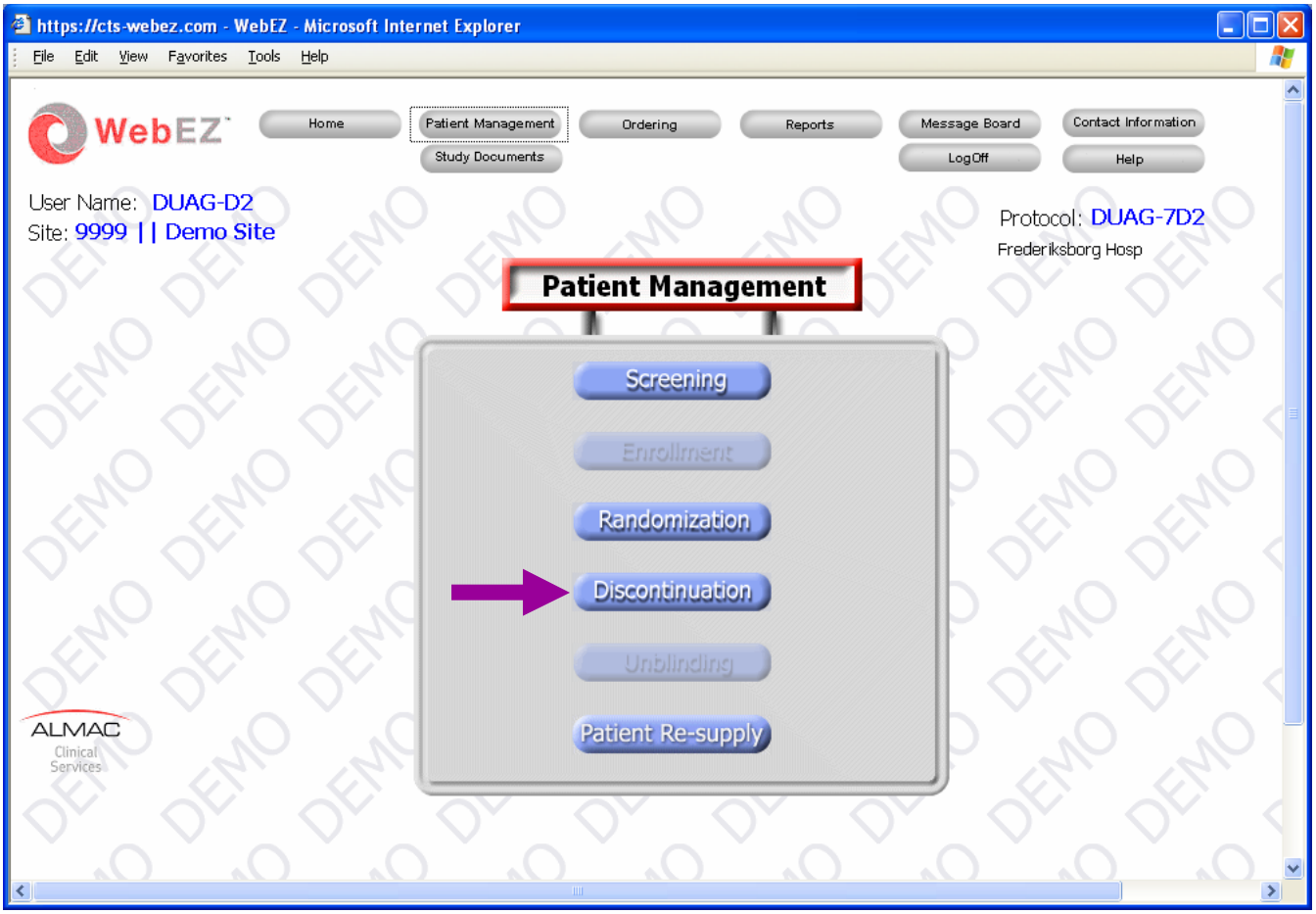


This report details both the kit number assigned at Randomization and the down titration kit number. Print the Patient Resupply History Report and retain with your source document records.

Click on ñCloseò to exit Resupply.

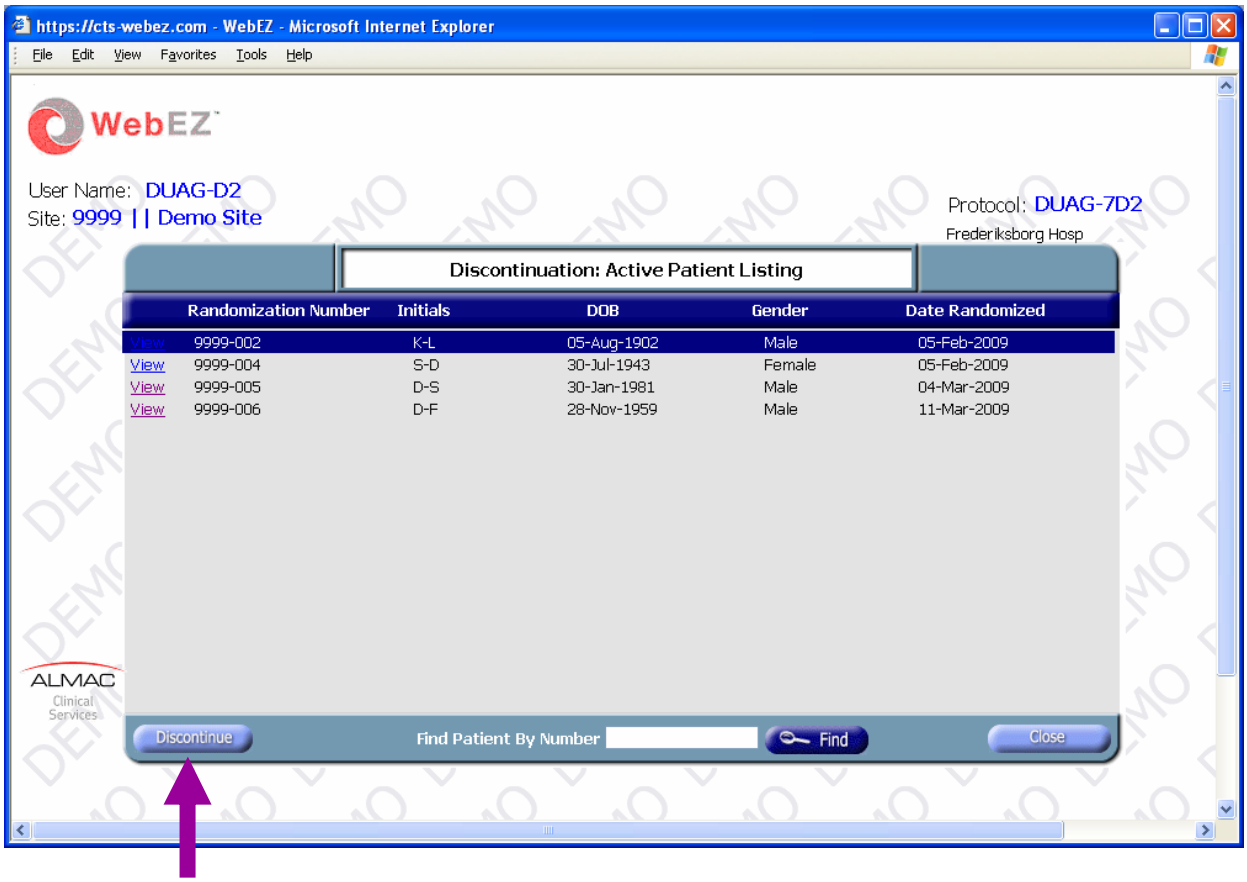

WebEZ - Microsoft Internet Explorer
File Edit View Favorites Tools Help
WebEZ
User Name: DUAG-D2
Site: 9999 | | Demo Site
Protocol: DUAG-7D2
Frederiksborg Hosp
Re-supply: Active Patients with Randomization Events
Randomization Number Initials DOB Gender Date Randomized
View 9999-002 K-L 05-Aug-1902 Male 05-Feb-2009
View 9999-004 S-D 30-Jul-1943 Female 05-Feb-2009
View 9999-005 D-S 30-Jan-1981 Male 04-Mar-2009
View 9999-006 D-F 28-Nov-1959 Male 11-Mar-2009
ALMAC Clinical Services
Patient Re-Supply
Find Patient By Number
Find
Close

In the event that a patient withdraws early from the study, first assign Down titration medication to the patient (Refer to p 26-32 for assignment of Down titration medication) and then in Patient Management click on ñDiscontinuationò.

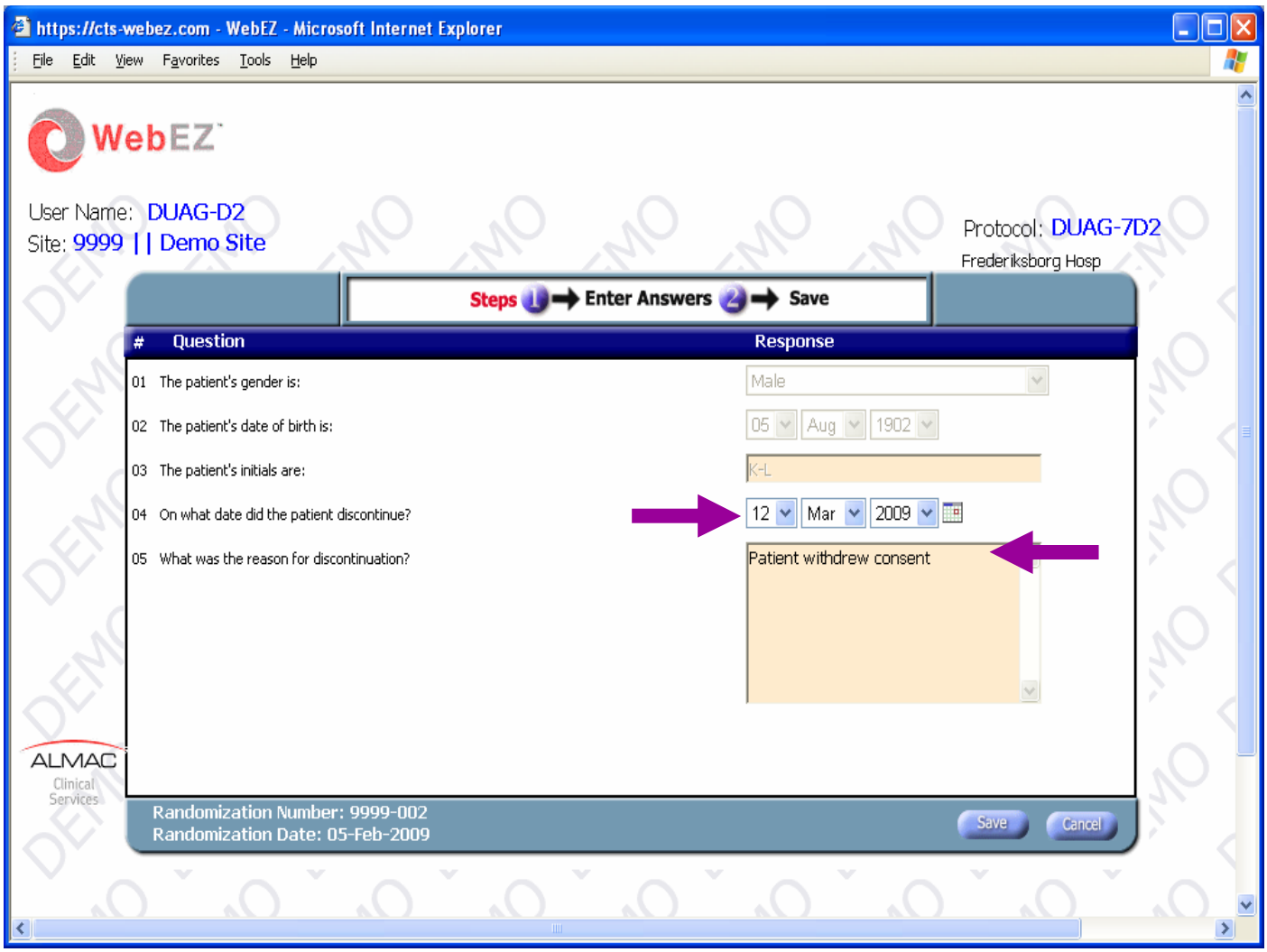


Discontinuation should only be used to indicate a patient that will not complete the trial not for patients that have completed the trial.

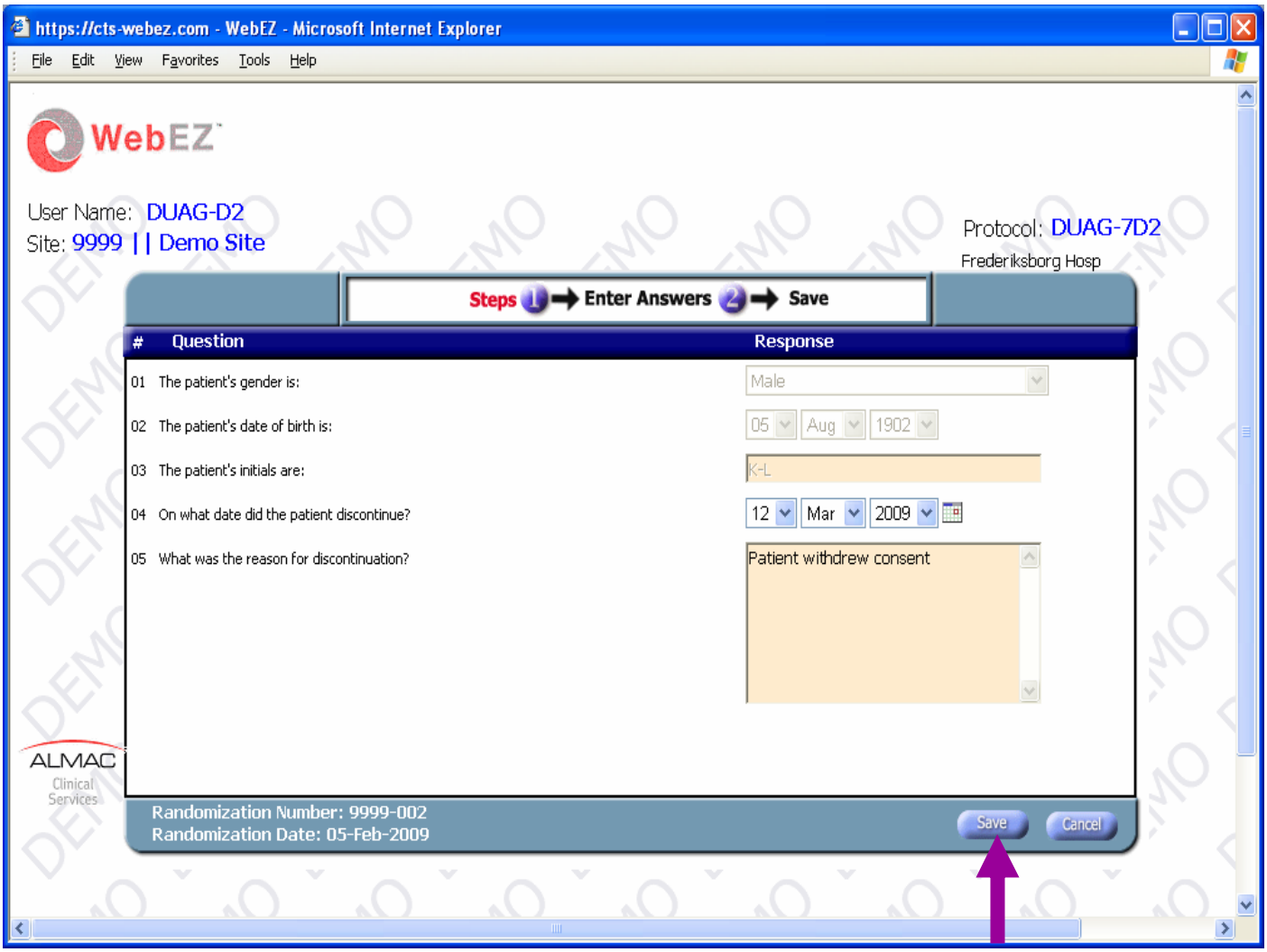
Click on the initials of the patient you want to discontinue. Only randomized patients will be listed. Click on ñDiscontinueò.



Enter the date the patient withdrew from the trial. This may differ from the date of the final follow-up contact or final visit assessment.
Enter the reason the patient will not complete the trial.



Click on ñSaveò.



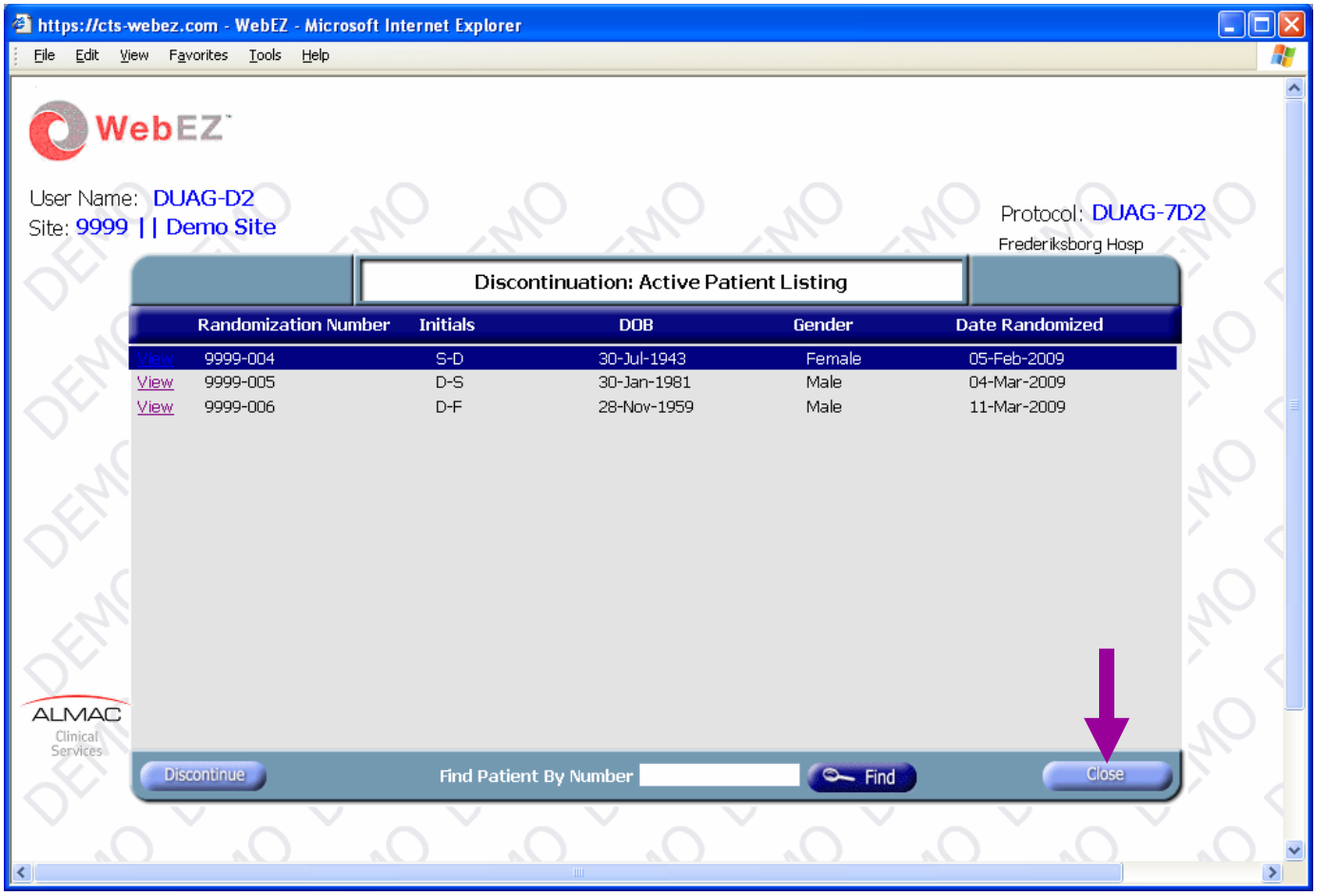
Once a patient is discontinued, it will not be possible to obtain down titration medication for that patient. If a patient is discontinued in error, please contact the WebEZ Helpline (806 000 03) to report the error.

After entering your e-signature, the Results window will appear confirming the patient has been discontinued from the trial.

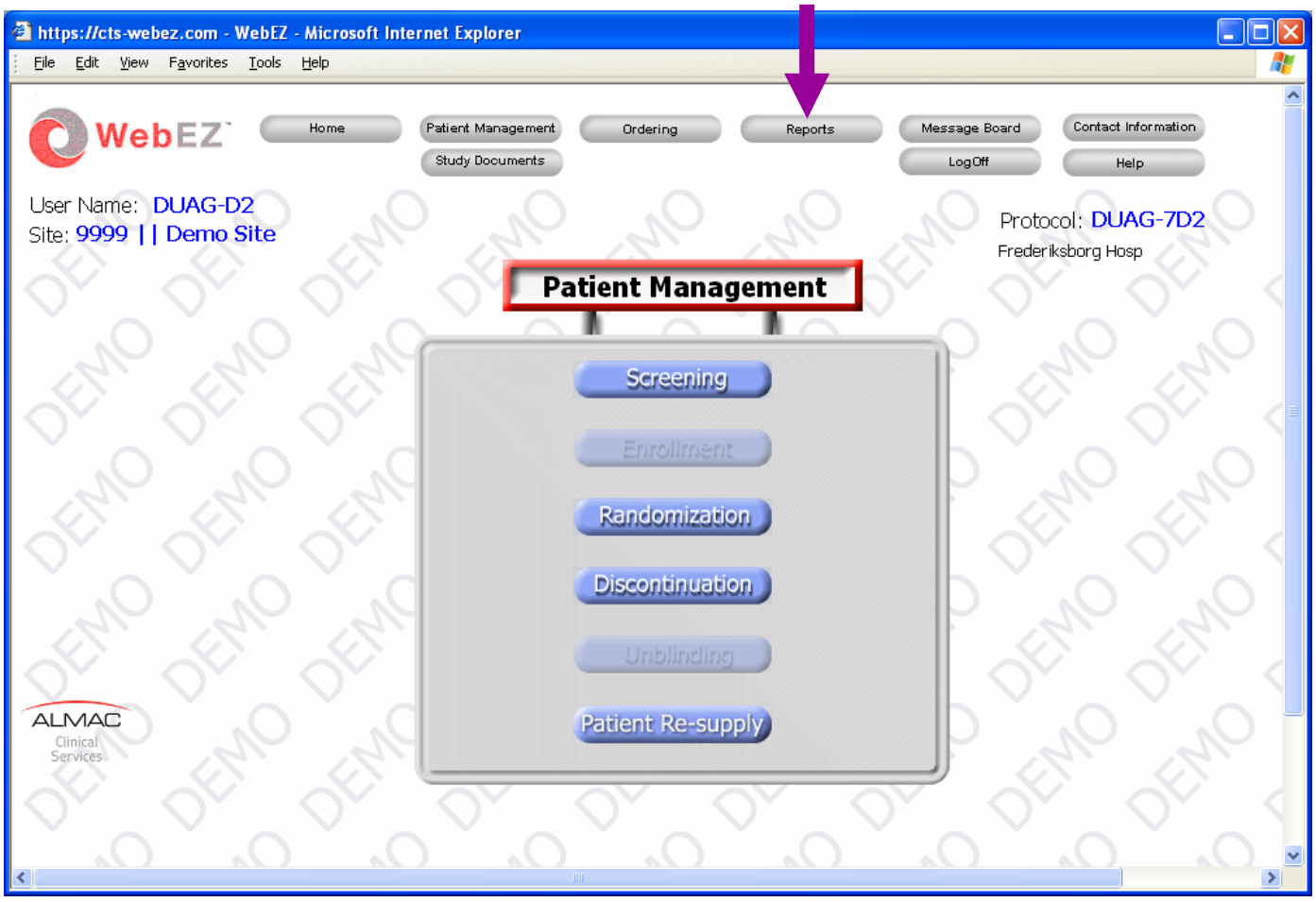
Please print the Results window and maintain with your source document records.

Click on ñCloseò to return to the active patient listing.

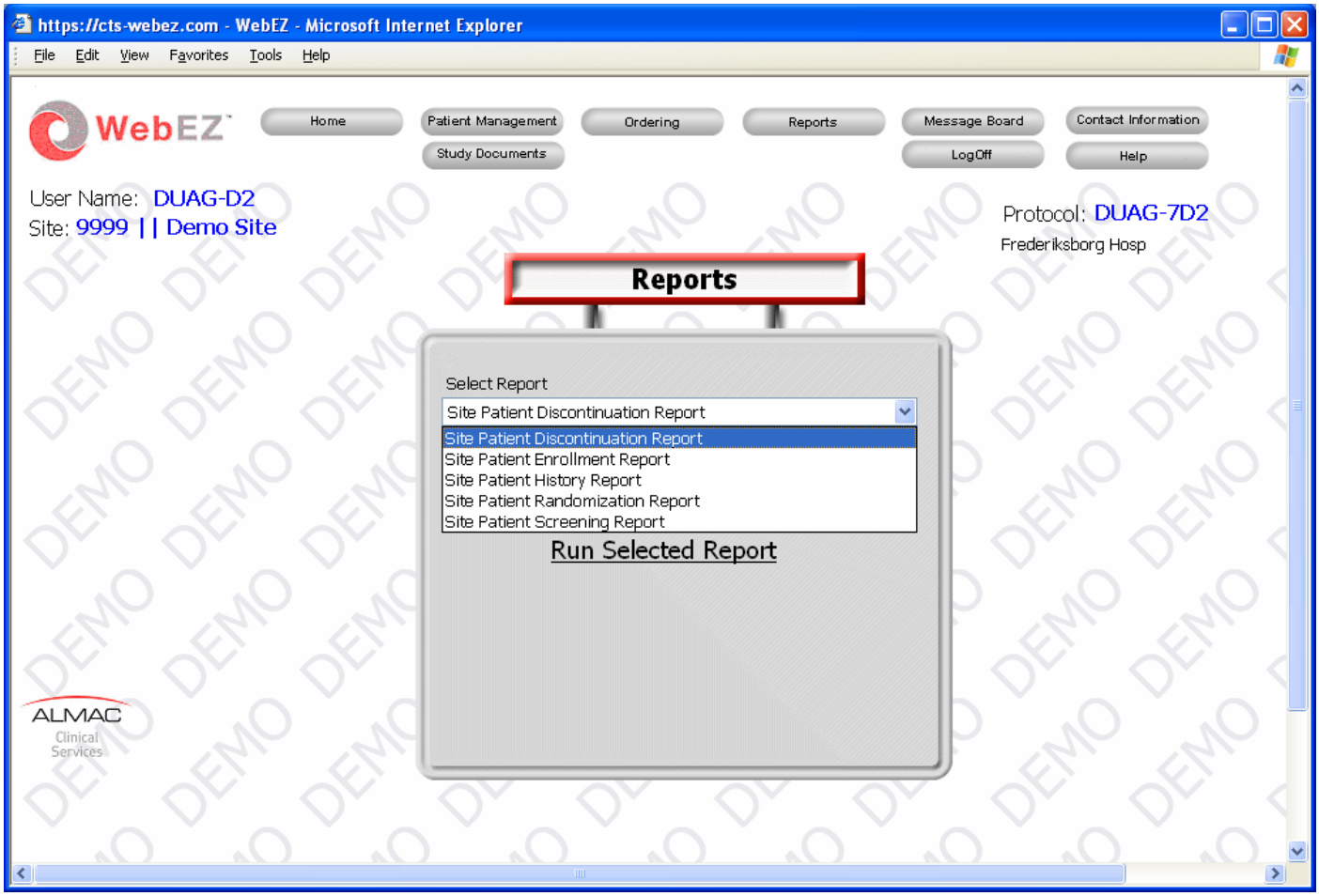
Click on ñCloseò to exit Discontinuation.



To run summary reports for your site, click on the ñReportsò button.



Use the Drop Down list to choose the report you wish to view. Click on ñRun Selected Reportò.

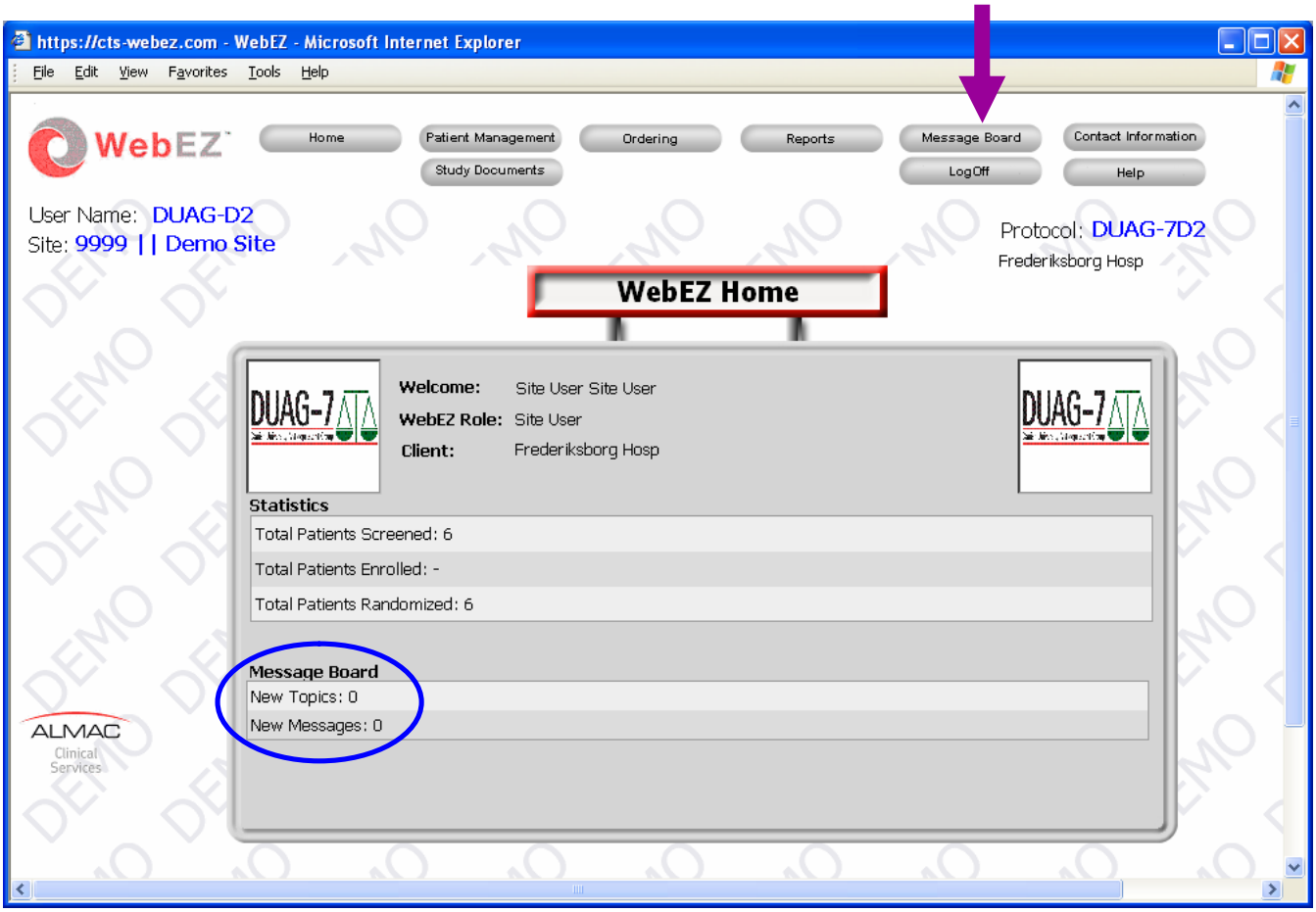


The Site Patient Randomization Report gives a summary of all patients at your site, including the patient number, date of birth, gender, kit assignment and date of randomization. The Site Patient Screening Report provides a summary of all patients screened at your site, including patient demographic data and the screening result (Pass or Fail). The site Patient Discontinuation Report provides a summary of all patients discontinued at your site, including the reason for discontinuation. The Site Patient History Report shows the screening, randomization, resupply and discontinuation data combined for all randomized patients.

The Enrollment Report will not have any data for your patient. The report will open but will be blank.

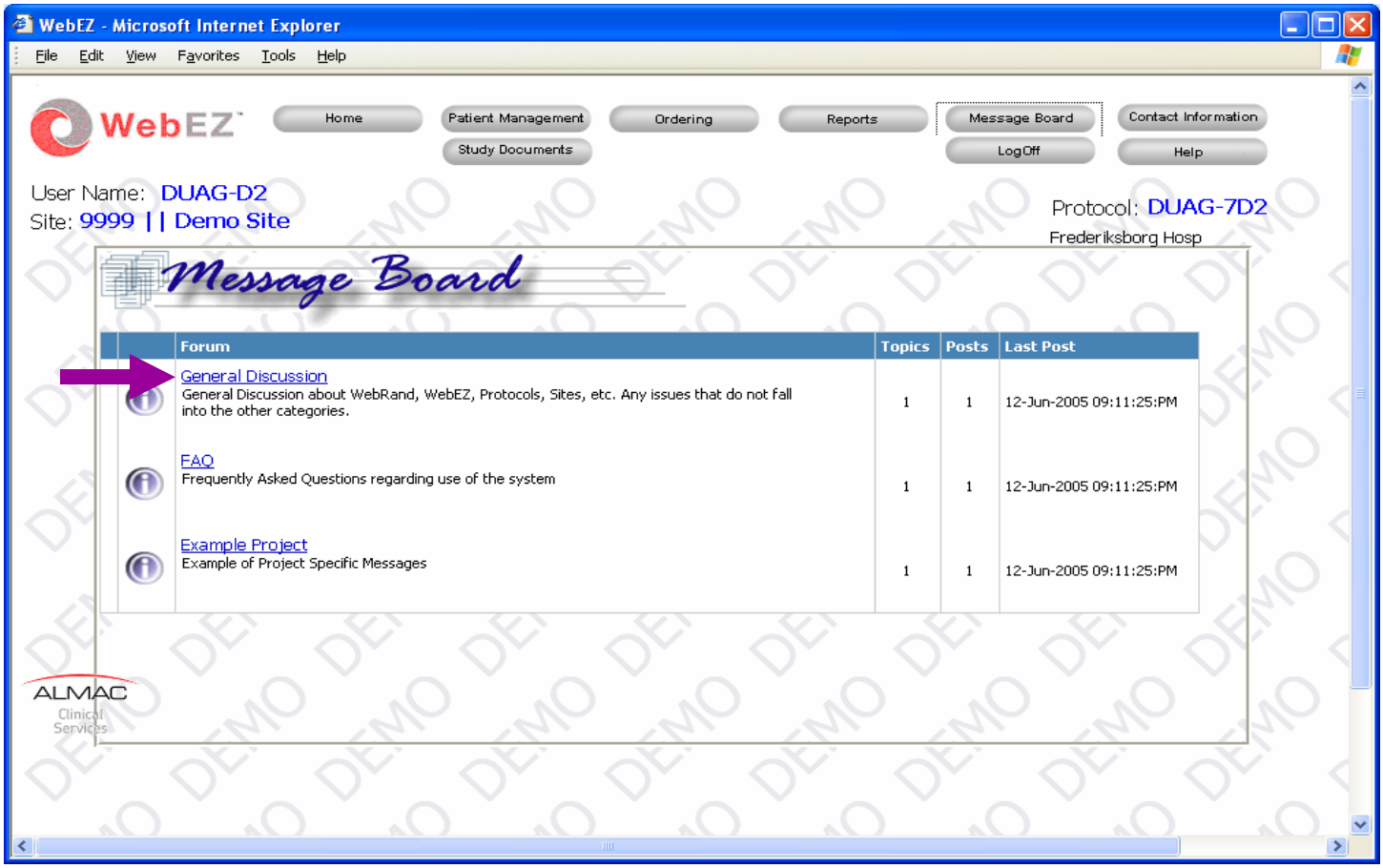
The reports will open in a new window as Adobe Acrobat (.pdf) files. The reports can be printed or saved for reference.

Click on ñMessage Boardò to view messages relating to the WebEZ message board.

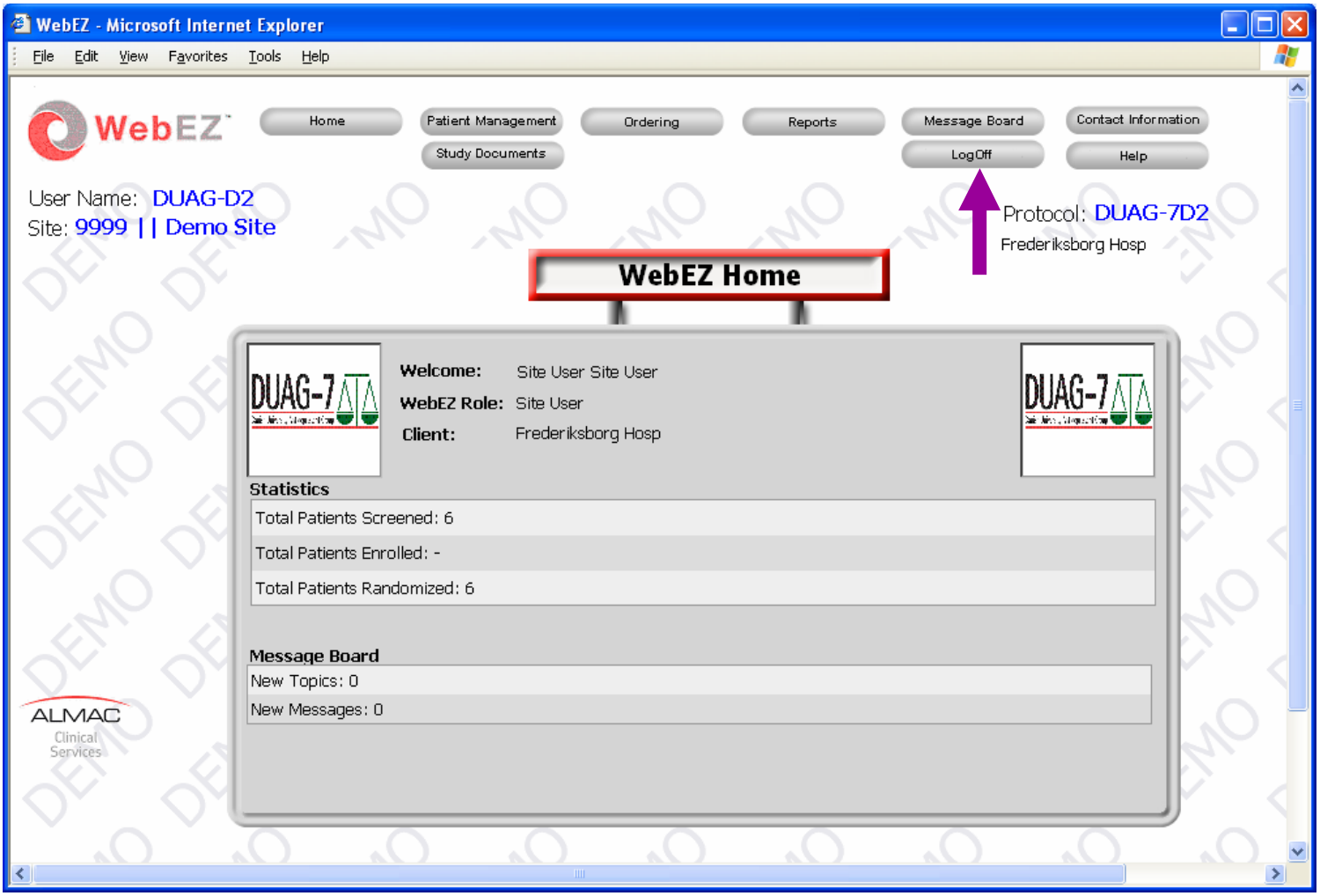


The Message Board alert on the Home Page will notify you of new messages that have been posted.

Click on the ñForumò e.g. General Discussion, you want to explore. A new window will open with related topics and specific messages that you can view.



To exit WebEZ, click on the ñLogoffò button.



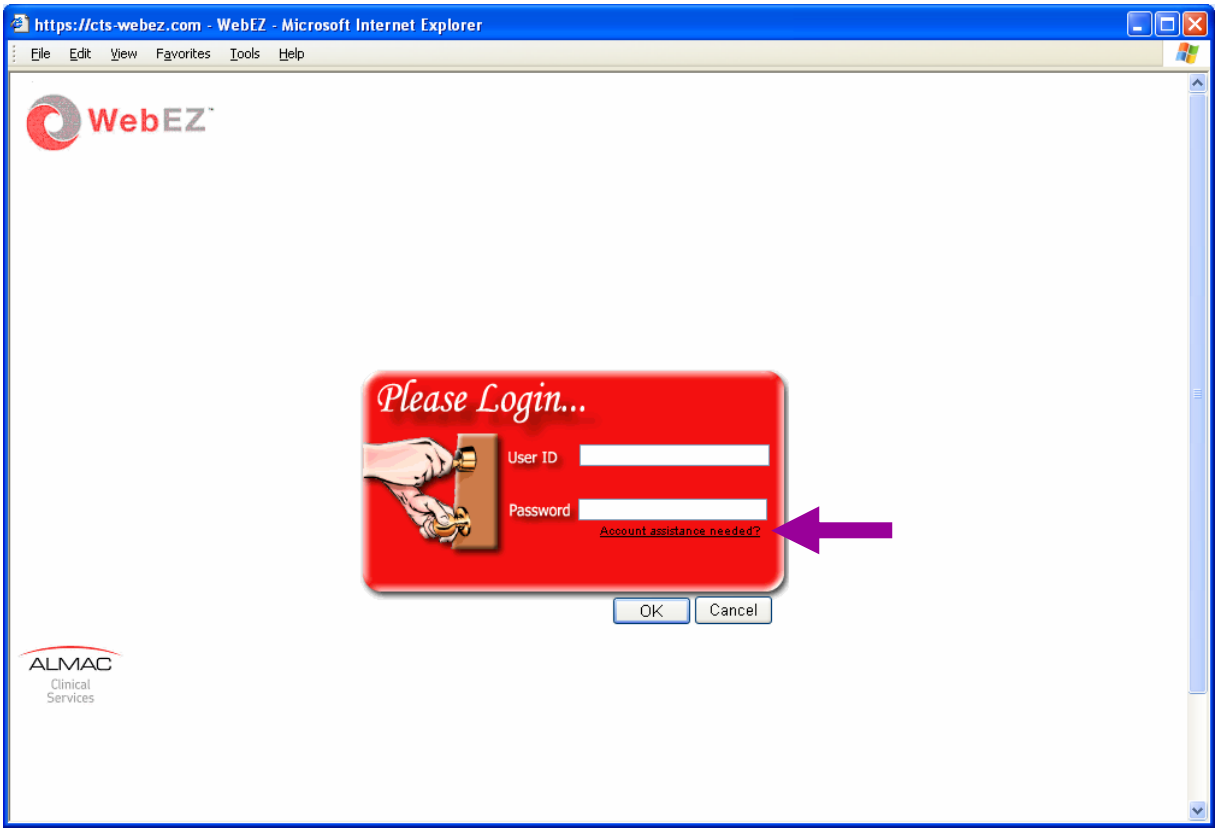
Helpful Hints:

You must disable your pop-up blocker for the WebEZ and WebEZ Demo sites.

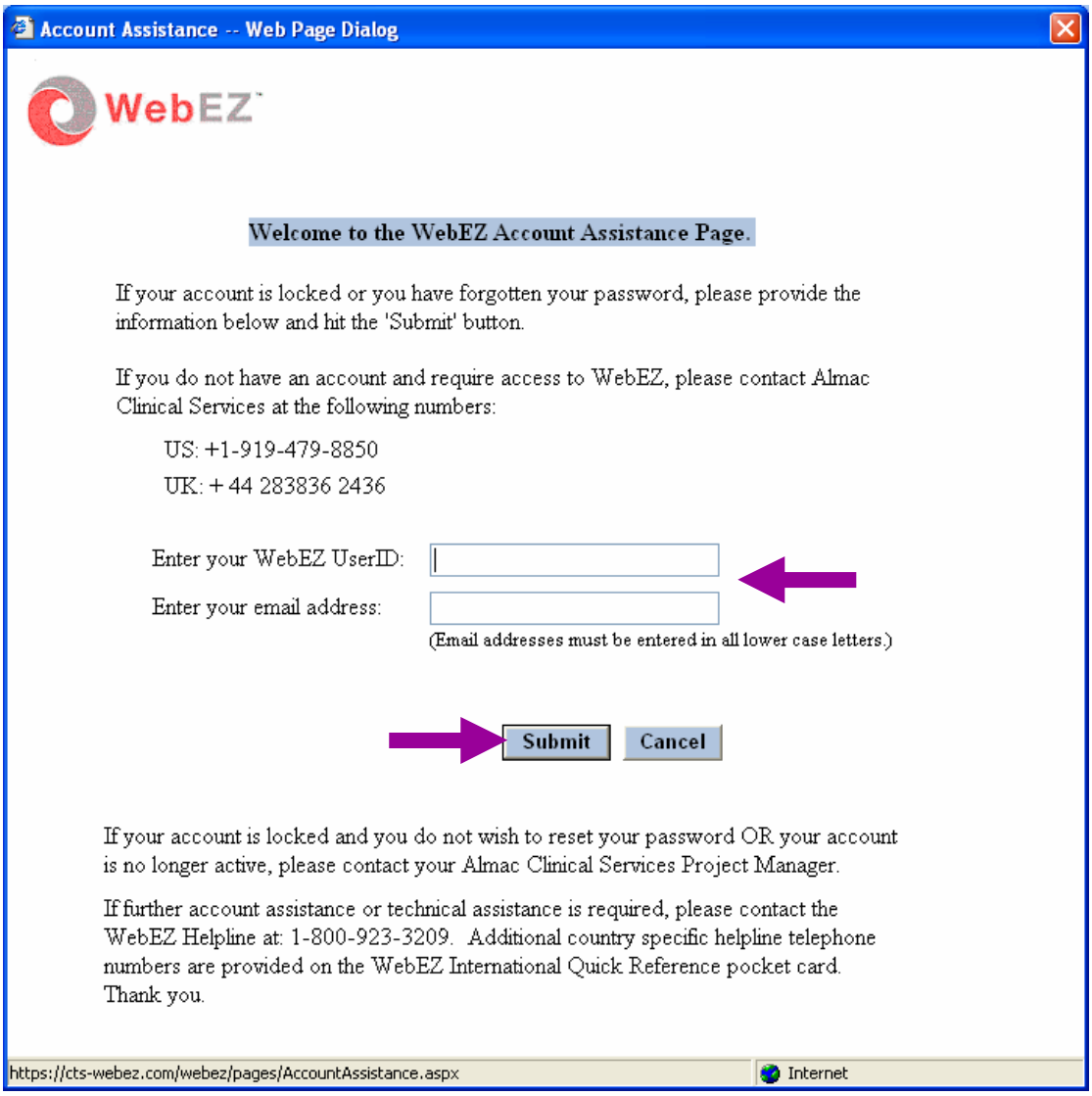
If you enter your password incorrectly 3 times, your account will be locked.

For technical support, 24 hours a day, 7 days a week, please call: 806 000 03.

If your account is locked, or you have lost your password, click on ñAccount assistance needed?ò

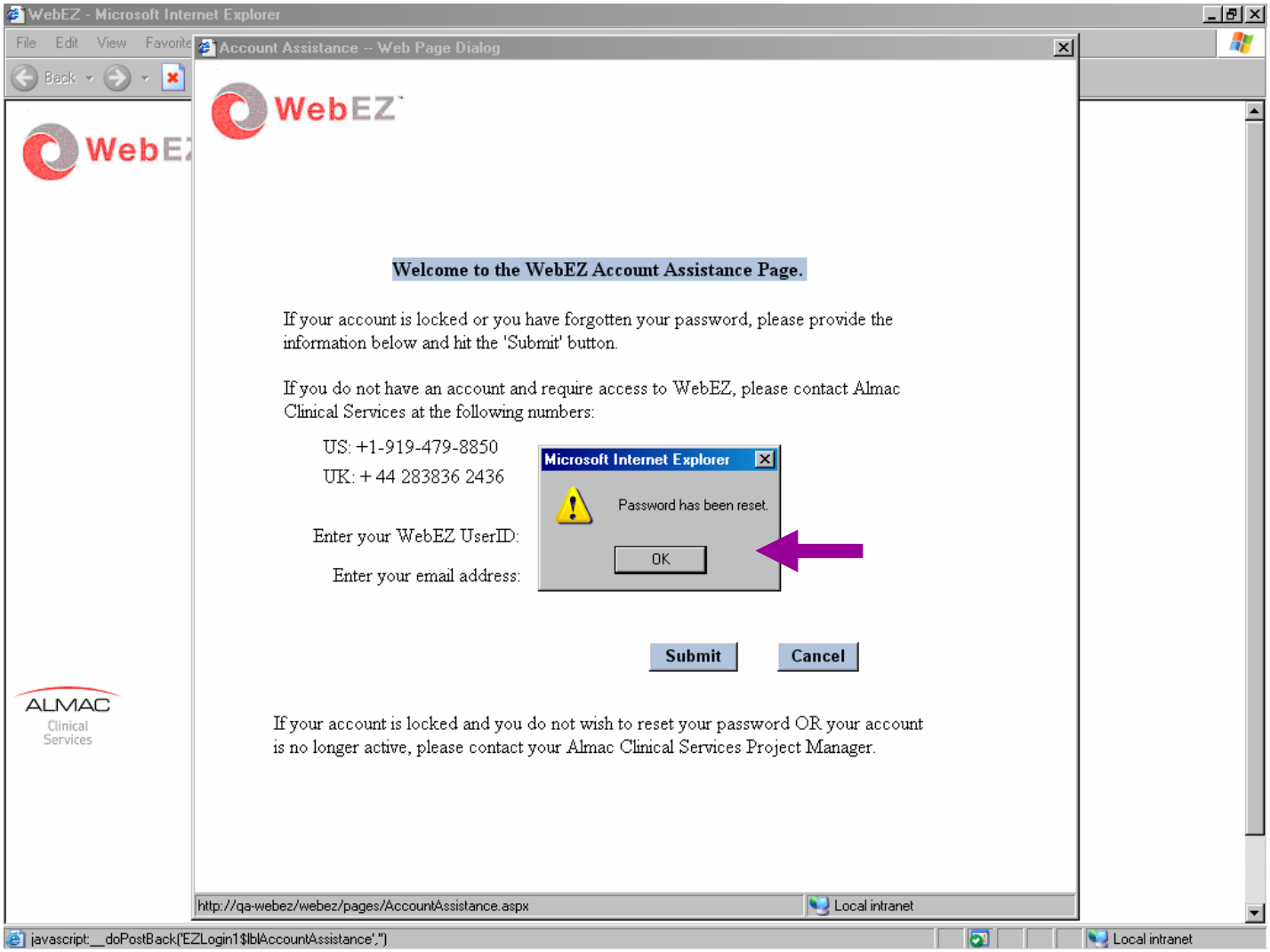


Enter your User ID and email address and click the ñSubmitò button.


Account Assistance -- Web Page Dialog
WebEZ
Welcome to the WebEZ Account Assistance Page.
If your account is locked or you have forgotten your password, please provide the information below and hit the 'Submit' button.
If you do not have an account and require access to WebEZ, please contact Almac Clinical Services at the following numbers:
US: +1-919-479-8850
UK: + 44 283836 2436
Enter your WebEZ UserID:
Enter your email address:
(Email addresses must be entered in all lower case letters.)
Submit
Cancel
If your account is locked and you do not wish to reset your password OR your account is no longer active, please contact your Almac Clinical Services Project Manager.
If further account assistance or technical assistance is required, please contact the WebEZ Helpline at: 1-800-923-3209. Additional country specific helpline telephone numbers are provided on the WebEZ International Quick Reference pocket card.
Thank you.
https://cts-webez.com/webez/pages/AccountAssistance.aspx
Internet

User IDs and E-mail addresses must be entered in all lower case letters.

The following window will appear to confirm that your password has been reset and your account has been unlocked.


WebEZ - Microsoft Internet Explorer
Account Assistance -- Web Page Dialog
WebEZ
Welcome to the WebEZ Account Assistance Page.
If your account is locked or you have forgotten your password, please provide the information below and hit the 'Submit' button.
If you do not have an account and require access to WebEZ, please contact Almac Clinical Services at the following numbers:
US: +1-919-479-8850
UK: + 44 283836 2436
Enter your WebEZ UserID:
Enter your email address:
Microsoft Internet Explorer
Password has been reset.
OK
Submit
Cancel
If your account is locked and you do not wish to reset your password OR your account is no longer active, please contact your Almac Clinical Services Project Manager.
http://qa-webez/webez/pages/AccountAssistance.aspx
Local intranet
javascript:__doPostBack('EZLogin1$lblAccountAssistance','')
Local intranet

Click ñOKò to return to the log in screen. You will receive the following e-mail containing your new temporary password that you can use to log into the system. You will be prompted to change your password the first time you log in.

```
Your WebEZ password has been reset.  The new password is listed
below.

Password: 4Iolx3P8

This is a courtesy e-mail sent to you by the Almac Clinical Services
WebEZ system.  Please do not respond to this e-mail.  If you have
questions, please contact your Almac Clinical Services Project
Manager.  Contact information can be found under the 'Contacts' menu
item in WebEZ.  Thank you.
```